

**COMPLIANCE GUIDELINES TO CONTROL
LISTERIA MONOCYTOGENES IN POST-LETHALITY EXPOSED
 READY-TO-EAT MEAT AND POULTRY PRODUCTS**

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A. Introduction

Food Safety and Inspection Service (FSIS) developed Compliance Guidelines to help the establishments producing Ready-to-Eat (RTE) meat and poultry products, especially small and very small establishments, in their use of control methods for *L. monocytogenes* to comply with the requirements of 9 CFR 430. Its purpose is to show establishments how the control methods can, if used singly or in combination, prevent or eliminate *L. monocytogenes* contamination in the product during post-lethality exposure. Establishments can use the guidelines to choose control methods that are best suited to their processing. Some establishments may have already instituted their control methods, which they have verified to be effective in controlling the pathogen and may not need to change their methods to follow these guidelines. However, FSIS will make a determination on the effectiveness of the controls and establishment verification testing when deciding how FSIS will conduct its verification procedures in the establishment.

The interim final rule applies only to post-lethality exposed RTE meat and poultry products. Products containing both raw and cooked ingredients (e.g., a frozen entrée containing blanched vegetables and fully cooked meat) will not be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, and (2) there are validated cooking instructions. A frozen product to be cooked may be either RTE or not ready-to-eat (NRTE) unless a food standard of identity requires that the product be RTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2.

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*These guidelines are being updated from the version posted on the FSIS website on October 6, 2003 to respond to comments and questions that FSIS received about the rule and to address questions that were asked during the workshops that the Agency held in preparation for the implementation of the interim final rule. **Added or revised sections are in color and in a different font.** The updated version includes:*

- *A table of contents that links the topics to the text by clicking the key words (in blue) (pp.1-2)*
- *Discussion of products covered by the rule under section on B. Control of *L. monocytogenes* Using Three Alternatives (p.6)*
- *Discussion of the following under section on Alternative 1*
 1. *Antimicrobial process that acts as a post-lethality treatment (p.9)*
 2. *Pre-packaging treatment as a post-lethality treatment (p.10)*
 3. *Post-lethality treatment not a Critical control Point (CCP) in the HACCP plan (p.10)*
 4. *Why an antimicrobial agent can be included in the HACCP plan, Sanitation SOP or prerequisite program (p.11)*
 5. *Hot packed products: edible oils and fats, lards, soups (p.11)*
 6. *Information on new approved levels of lactates and diacetates (p.12)*

- 7. Table on Growth Limits -included °F temperature (p.13)
- 8. Products with post-lethality treatments under Alternatives 1 and 2, and a positive food contact surface test (p.15)
- Discussion under section on Alternative 3
 - 1. Products considered as deli and hotdog products (p.19)
- Discussion of labeling issues under section on Labeling
 - 1. Generic label approval (p.22)
 - 2. Approval of labels bearing claims (p.23)
 - 3. Antimicrobial agents in comminuted beef product (p.23)
 - 4. Reclassification of products that are RTE as NRTE (p.24)
- Discussion under section on Sanitation
 - 1. Section V. Discussion on separation of raw and cooked areas (p.32)
 - 2. Section VI. Discussion of control during construction activities (pp. 34, 38)
 - 3. Section VII-1. Positive FCS for products with post-lethality treatments (pp.40, 41)
 - 4. Section VII-3. Reference to rapid screening methods and discussion on methods that are not evaluated by a recognized body. (p.45)
 - 5. Section VII-4. Discussion on Hold and Test Scenario (p.46)
- Discussion in Attachments
 - 1. Attachment 3. Production Information on Post-lethality Exposed Ready-to-Eat Products Sample Form (p.60)
 - 2. Attachment 4. Added discussion of acidified sodium chlorite as antimicrobial agent (p.66)
 - 3. Attachment 5. Added Cases 10, 11, 12 to the ICMSF Sampling Plan (p.75-76)
 - 4. Attachment 6. Revised flowchart and discussion on hold and test scenario (p.78, 81)

These guidelines will be updated periodically to include validated and other effective procedures as they become available.

B. Control of *Listeria monocytogenes* Using Three Alternatives

Listeria monocytogenes is a pathogen that is widely distributed in the environment such as plants, soil, animal, water, dirt, dust, and silage. Because *L. monocytogenes* may be present in slaughter animals and subsequently in raw meat and poultry as well as other ingredients, it can be continuously introduced into the processing environment. The pathogen can cross-contaminate food contact surfaces, equipment, floors, drains, standing water and employees. In addition, the pathogen can grow in damp environments and can establish a niche and form biofilms in the processing environment that are difficult to eliminate during cleaning and sanitizing. Other characteristics of *L. monocytogenes* that

makes it a formidable pathogen to control are its heat and salt tolerance and its ability to grow at refrigeration temperatures and survive at freezing temperatures.

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products generally eliminates *L. monocytogenes*; however products can be re-contaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other procedures. Several outbreaks of foodborne illness resulting in hospitalization, miscarriage, stillbirth, and death have been linked to the consumption of deli meats and hotdogs containing *L. monocytogenes*. One of the most likely causes of *L. monocytogenes* contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Deli and hotdog products are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, but are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If *L. monocytogenes* is present on the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. These products are examples of RTE meat and poultry products that can support the growth of *L. monocytogenes* during refrigerated storage. Since RTE products are consumed without further cooking, if they are contaminated, there is a possibility of the occurrence of foodborne illness. The “FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods” (www.foodsafety.gov/~dms/lmr2-su.html) indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from *L. monocytogenes*.

RTE meat and poultry processing plants must include control programs for *Listeria monocytogenes* in their HACCP plans, Sanitation SOP or prerequisite programs to prevent its growth and proliferation in the plant environment and equipment, and prevent the cross-contamination of RTE products. The FSIS *Listeria* risk assessment (www.fsis.usda.gov/OPHS/lmrisk/DraftLm22603.pdf) indicated that the use of a combination of intervention methods to control *L. monocytogenes* in deli meats exposed to the environment after the lethality treatment has the greatest impact on lowering the risk of illness or death from *L. monocytogenes*. The Agency used these risk assessments as resources in developing the regulations to control *L. monocytogenes* in RTE meat and poultry processing.

The interim final rule for the control of *Listeria monocytogenes* (9 CFR 430) includes three alternative approaches that establishments can take in the processing of RTE meat and poultry products during post-lethality exposure. Under Alternative 1, an establishment applies a post-lethality treatment and an antimicrobial agent or process to control *L. monocytogenes*. Under Alternative 2, an establishment applies either a post-lethality treatment or an antimicrobial agent or process. In Alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process. Instead, it relies on its sanitation program. Products produced under Alternative 1 and 2 are formulated and processed to eliminate *L. monocytogenes* and/or limit its growth if it is present. That means the number of organisms shall not increase during the product’s shelf life to detectable levels, or levels which may result in a public health hazard. These alternatives provide greater control compared to Alternative 3 which

involves only sanitation to control *L. monocytogenes*. Consequently, the rigor or stringency of the control methods decreases from Alternative 1 to 3. An establishment must identify which alternative their RTE product falls into based on its control program for *L. monocytogenes*. An establishment can choose to apply new control methods and subsequently move from one alternative to another; however, it must apply the control methods required for the specific alternative that it moved into. Each alternative has specific requirements with which the establishment must comply. A systematic table of the requirements for each alternative can be found in Attachment 1.

FSIS recognizes that establishments may be producing products that fall under different alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance. Conversely, products processed according to different alternatives, may be covered by a single HACCP plan. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hot dogs formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences. In addition, if an establishment uses the same food contact surfaces (FCS) on the same production day (clean-up to clean-up) for products falling within two alternatives, the products should be treated as if they were in the higher risk category with respect to on-going verification by the establishment, including testing of product, food contact surfaces and the environment.

Products Covered by the Listeria rule:

Establishments should determine the alternatives to which it will adhere in its processes. The following steps can guide establishments in making this decision:

- *Determine whether product is RTE or not RTE (NRTE). Resource 1 of the Directive and Attachment 2 of these Compliance Guidelines can guide the establishment in determining whether its product is RTE or NRTE. NRTE products are not covered by the rule.*
- *If the product is RTE, the establishment should determine whether the product is exposed to the environment after the lethality treatment (e.g., cooking) and before packaging. Examples of exposure to the environment after the lethality treatment are the following: 1) when product is removed from its cooking bag and re-packaged; 2) when product is removed from the cooking bag and sliced or cut-up and re-packaged; or 3) when product is peeled and repackaged; or when it is fermented or salt-cured or dried and smoked and packaged. (e.g., roast beef, cooked ham for slicing, hotdogs, fermented sausage, cured ham, and jerky).*

- *If the product is not exposed to the environment after the lethality treatment and before packaging, then the product is not covered by the Listeria rule. Examples of these products are fully cooked product in cook-in-bag that leaves the official establishment in the intact cooking bag; products receiving a lethality treatment and hot-filled, thermally processed commercially sterile products.*
- *If the product is post-lethality exposed, the establishment should determine the control methods it is using to control *L. monocytogenes* during the post-lethality exposure. The control methods used by the establishment will determine to what alternative the product can be categorized.*

1. Alternative 1

Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent or process) to reduce or eliminate *L. monocytogenes* and an antimicrobial agent or process to suppress or limit the growth of the pathogen. For RTE products that are cooked and then removed from their cooking bag and sliced, diced or repackaged, there is a risk of cross contamination from the equipment, conveyor belts and the processing environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from *L. monocytogenes*.

a. Post-Lethality Treatment

Post lethality treatments such as steam pasteurization, hot water pasteurization, radiant heating and high pressure processing have been developed to prevent or eliminate post-processing contamination by *L. monocytogenes*. RTE products where post-lethality treatments were shown by studies to be effective in reducing the level of *L. monocytogenes* are whole or formed ham, whole and split roast beef, turkey ham, chicken breast fillets and strips, and sliced ham, sliced turkey, and sliced roast beef.

Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Ultra violet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces or suppresses growth of *L. monocytogenes*. Some of the published studies on post-lethality treatments are reviewed in Attachment 4. Studies on post-lethality treatments showed reductions of inoculated *L. monocytogenes* from 1 to 7 log₁₀ CFU/g depending on the product type, and duration, temperature and pressure of treatment. Higher log reductions were obtained when both pre-packaging and post-packaging surface pasteurizations were applied, and when post-lethality pasteurization was combined with the use of antimicrobial agents. Establishments should refer to the details of these studies if they want to use the intervention method in their processing. The guidelines will be updated to include studies or other methods as they become available.

Validation of Post-lethality Treatment

The post-lethality treatment that reduces or eliminates the pathogen must be included in the establishment's HACCP plan. The post-lethality treatment must be validated according to 9 CFR 417.4 as being effective in eliminating or reducing *L. monocytogenes* to undetectable level, and the validation should specify the log reduction or suppression achieved by the post-lethality treatment and antimicrobial agents. The effectiveness of the post-lethality treatments and antimicrobial agents must be verified, and establishments should make the verification results available to FSIS personnel upon request. FSIS expects the establishment's HACCP documentation to demonstrate that the post-lethality treatment is adequate to eliminate or reduce *L. monocytogenes* to undetectable level. In cases of pre-packaging treatment, the establishment must be able to demonstrate how the level of contamination that may occur before packaging is eliminated.

An establishment can use available published research studies as reference for their validation provided these studies use the product type or size, the type of equipment, time, temperature, pressure and other variables used in the study in order to result in equivalent level of reduction of *L. monocytogenes*. An establishment that uses products, treatments or variables other than those used in the referenced studies must perform its own validation studies to determine the effective reduction of *L. monocytogenes* as a result of the post-lethality treatment or antimicrobial agent applied to the products. Some of the published studies use different products and report a range of levels of reduction of *L. monocytogenes*. In this case, the establishment must validate the use of the post-lethality treatment or antimicrobial agent for its specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in its validation to show that the product is safe. In the absence of published peer-reviewed paper that would contain information needed for validation, unpublished studies may be used provided there is supporting documentation that the data and analysis of results demonstrate that the specific level of application on specified products or range of products is effective to produce a safe product. In addition to the validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for *L. monocytogenes*.

Antimicrobial Process that Acts also as a Post-lethality Treatment

An example of an antimicrobial process that controls the growth of L. monocytogenes in the post-lethality environment is a lethality process that renders a RTE product shelf stable. Shelf stable products are formulated with salt, nitrites and other additives, and processed to achieve a water activity, pH and moisture-protein ratio that will reduce the level of L. monocytogenes and other pathogens during processing. In addition, the lethality treatment exerts a continuing bactericidal and bacteriostatic effect in the product, enabling the product to not support the growth of L. monocytogenes and other pathogens during the shelf life of the product at ambient temperatures.

Since products with water activity less than 0.85 will not support the growth of L. monocytogenes and can sometimes even cause L. monocytogenes death, FSIS will consider water

activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a bactericidal effect (death of bacterial cells leading to a reduction in number) in the specific product, and the establishment has provided support documentation to document that the intended effect occurs prior to distribution of the product into commerce. In this case, the antimicrobial process could serve as both a post-lethality treatment and growth inhibitor. The establishment should have documentation on file (e.g., copy of a published report, challenge study) to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. These shelf stable products can be classified in Alternative 1 if the requirements for this alternative are satisfied. The requirement that an antimicrobial process or product formulated with an antimicrobial agent suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. Establishments must include in their HACCP plans the antimicrobial process used (e.g. drying, cooking/frying, or rendering) and the water activity achieved that renders the product shelf stable. Examples are shelf stable RTE jerky, country cured ham, pepperoni, dried soups, and pork rinds.

Pre-packaging Treatment as a Post-lethality Treatment

A pre-packaging treatment such as radiant heating can be used as a post-lethality treatment as long as it is validated to eliminate or reduce the level of *L. monocytogenes*. Since this is a post-lethality pre-packaging treatment, there is possible exposure to the environment after the treatment and before packaging. If there is separation between the treatment and packaging, then conditions have to be met to ensure a hygienic environment to preclude contamination, or the post-lethality treatment would not likely be considered effective by FSIS. Some establishments may place the packaging machine right after the radiant heat treatment to reduce or eliminate this exposure. Support documentation must be made a part of the hazard analysis decision-making documents and validation data must be included in the HACCP plan. Studies have also shown that the use of pre-packaging treatment combined with a post-lethality treatment resulted in a higher log reduction of the pathogen.

Post-lethality Treatment Not a Critical Control Point (CCP) in the HACCP Plan

The rule states that *L. monocytogenes* is a hazard reasonably likely to occur for post-lethality exposed product unless there is a control measure incorporated in the HACCP plan, prerequisite program or Sanitation SOP. For Alternative 1 or Alternative 2 (post-lethality treatment) control measures, if a post-lethality treatment is used, it must be included in the establishment's HACCP plan as a CCP. FSIS

encourages the use of any effective intervention for controlling *L. monocytogenes* contamination. However, if an establishment uses a post-lethality treatment for its product but does not incorporate the post-lethality treatment as a CCP, the post-lethality treatment cannot be used to justify Alternative 1 or 2 (post-lethality treatment). It could place the control measures for the operation in the Sanitation SOP or prerequisite program and the product can be categorized in Alternative 2 (antimicrobial agent) or Alternative 3.

Why an Antimicrobial Agent can be included in the HACCP Plan, Sanitation SOP or prerequisite program.

If an establishment chooses Alternative 2 and chooses to use an antimicrobial agent or process, the establishment can include the antimicrobial agent or process as a CCP in the HACCP plan, in the Sanitation SOP, or in a prerequisite program. The Agency gave establishments this flexibility because the Agency believes that how establishments choose to address control of *L. monocytogenes* will determine how they fit in the hierarchy. Antimicrobial agents or processes do not necessarily eliminate or reduce a food safety hazard from occurring but rather control for the hazard, by preventing or suppressing the growth of *L. monocytogenes*. A post-lethality process is applied at a specific step in the process that eliminates, reduces to an acceptable level, or prevents a food safety hazard, i.e., a critical control point. However, when the antimicrobial agent does eliminate or significantly reduce *L. monocytogenes*, it could be designated a CCP in the HACCP plan. On the other hand, if it only suppresses growth of *L. monocytogenes*, it could be addressed in the Sanitation SOP or other prerequisite programs.

Hot-packed products: edible oils and fats, lard, soups

Edible oils and fats that result from a rendering process that processes them to 180° F and maintains at 160° F, with a water activity of less than 0.2 making them shelf stable are considered RTE. Rendering is intended to make this meat food product a ready-to-use ingredient in the preparation of other foods, e.g., edible tallow and lard are used as shortening. They do not require additional lethality treatment before being consumed. If these products are hot filled and packaged, they are not considered post-lethality exposed and therefore are not covered by the rule. These products would be considered NRTE and not covered by the rule if the process calls for partially rendering animal fat for tallow or lard and then further processing or finished rendering in another plant.

Soups and other products that are cooked to eliminate pathogens and hot-packed in the final packaging material are

RTE, but are not considered post-lethality exposed. Therefore the Listeria rule does not apply.

b. Antimicrobial Agents or Processes

Antimicrobial agents and processes must suppress or limit the growth of *L. monocytogenes* throughout the product shelf life i.e., the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. Antimicrobial agents were shown in research studies to reduce the levels of *L. monocytogenes*. These include lactates and diacetates added in the formulation and growth inhibitors in the immediate packaging material. These were shown to be effective in the control *L. monocytogenes* in RTE products such as hot dogs, bologna, cotto salami, and bratwurst.

Antimicrobial agents can be added to the product during formulation, to the finished product or to the packaging material to inhibit growth of *L. monocytogenes* in the post-lethality exposed product during its refrigerated shelf life. Lactates and diacetates are some antimicrobials added to the formulation of RTE meat and poultry products. Establishments should use antimicrobial agents that have been approved by FDA and FSIS for processed RTE meat and poultry products.

FSIS recently increased the permissible levels of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 % (65 FR 3121-3123/2000). The rule also permitted the use of sodium lactate and potassium lactate in fully cooked meat, meat food products, poultry, and poultry food products, except for infant foods and formulas at levels of up to 4.8 % of total product formulation for the purpose of inhibiting the growth of certain pathogens. Approved antimicrobials for processed meat and poultry products can be found in 9 CFR 424.21 and in Directive 7120.1. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label.

Studies on antimicrobials added to the packaging material or active packaging showed about 1-2 log₁₀ CFU/g reduction of *L. monocytogenes* during the refrigerated shelf life of the products. Based on published studies, growth reduction or inhibition achieved by adding these antimicrobials to product formulation depends on a variety of factors, such as the level of antimicrobial agent added, product formulation and whether the agent was added during formulation or to the finished product. Depending on the amount of antimicrobials and other growth inhibitors added to the product formulation and other ingredients in the product, growth inhibition of *L. monocytogenes* was shown to range from 30 days to 120 days at refrigerated temperatures. Some published studies on antimicrobials are reviewed in Attachment 4. Establishments should refer to the details of the studies if they want to use the intervention method in their processing.

An establishment that uses agents that inhibit *L. monocytogenes* on equipment and food contact surfaces in addition to using growth inhibitors in the product formulation can

qualify the product for Alternative 2 using antimicrobial agents. Using these inhibiting agents on equipment and food contact surfaces can be considered as part of the sanitation program. These inhibiting agents applied to equipment and food contact surfaces must be GRAS and approved by FDA.

Antimicrobial Processes

Some RTE products with added salt, nitrites and other additives achieve a water activity, pH, or moisture-protein-ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing and continue to inhibit the growth of the pathogens during the refrigerated shelf life. These products are not shelf stable because they need to be refrigerated during their shelf life, but because of the water activity and pH attained during the initial lethality treatment, these products may not support the growth of *L. monocytogenes* during its refrigerated shelf life. These products can be classified as using an antimicrobial agent or process. Examples of these products are RTE, not shelf stable fermented sausages and country cured hams.

Another antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their metabolic activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Like other microorganisms, *L. monocytogenes* is resistant to freezing. Once the product is thawed, metabolic activities of microorganisms may resume, depending on whether the microorganisms are killed, injured, or not affected at all. Therefore this antimicrobial process is only effective while the product is frozen. The requirement that a product remain frozen throughout its shelf life therefore excludes situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process by the consumer, the product will be deemed to have been frozen throughout its shelf life. Labels of RTE frozen products contain cooking instructions for the frozen product and for thawed and refrigerated product, and instructions for thawing at refrigerated temperatures. Examples of frozen RTE products are fully cooked frozen chicken nuggets, fully cooked frozen chicken breast patties or fully cooked frozen dinners.

The chart below shows the growth limits for *L. monocytogenes*. These limits represent scientific consensus as to the temperature, pH, and water activity levels for *L. monocytogenes* (ICMSF, 1996). The pathogen can grow between the minimum and maximum levels. The minimum growth limits represent the lowest levels below which the pathogen cannot grow. Establishments with processes that achieve levels below the minimum limits can use these as their control for the pathogen. Establishments that comply with the levels below the minimum growth parameters need not conduct further validation for their products to prove that growth is inhibited to less than 1-log throughout the shelf-life of the product. The establishment can place the attached reference on file in their control program documentation. However, the establishment should conduct on-going monitoring and verification activities to demonstrate that they are maintaining the conditions for pH, water activity, or temperature.

Growth limits for *Listeria monocytogenes* (ICMSF, 1996)

	Minimum	Optimum	Maximum
Temperature	-0.4 °C (31.3 °F)	37 °C (98.6°F)	45 °C (113 °F)
pH	4.39	7.0	9.4
Water activity	0.92	---	---

The antimicrobial agent or process that limits or suppresses *L. monocytogenes* must be included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment must have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the program must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment must include the program and the results produced by the program in the documentation that the establishment maintains as required in 9 CFR 417.5.

The establishment must include supporting documentation to show the effectiveness of the antimicrobials in suppressing or limiting *L. monocytogenes* in the HACCP plan, Sanitation SOP or prerequisite programs. An establishment can use published studies as reference for its validation and supporting documentation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents and products, concentration, time and temperature of effectiveness. Use of antimicrobial singly or in combination, with different concentration and other variables, and for products not used in the studies must be validated or tested for their effectiveness. This must be validated for the HACCP plan, or documented in the Sanitation SOP or other prerequisite programs. The establishment must verify that the antimicrobial program is effective by testing product for *L. monocytogenes* and must verify that it does not cause the hazard analysis or the HACCP plan to be inadequate. That is, an effective prerequisite program will reduce the likelihood of occurrence of a hazard so that the product is safe. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analysis and therefore a CCP for the hazard may not be needed. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L. monocytogenes* does not become a hazard reasonably likely to occur.

An establishment with products in Alternative 1 must maintain sanitation in the post-lethality processing environment in accordance with Part 416. The establishment must make available upon request to FSIS inspection personnel, the verification results that demonstrate the effectiveness of its controls, whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program. The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the establishment should investigate the potential source of the positive finding, take corrective actions to eliminate the source, and verify the effectiveness of the corrective actions. In certain situations, the source of *Listeria* may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the area tested.

FSIS considers a product to be adulterated if a food contact surface, such as a surface of an equipment used in the production of the product, tests positive for L. monocytogenes. However, if a RTE post-lethality exposed product receives a post-lethality treatment (Alternative 1 or Alternative 2), that product which came in direct contact with a food contact surface that tested positive for L. monocytogenes would not summarily be considered adulterated. This is because the post-lethality treatment should have been validated and documented in the establishment's HACCP plan to be effective in eliminating or reducing L. monocytogenes. Without such validation and documentation, the establishment would have to present compelling argument for why the post-lethality treatment was effective for the Agency to conclude that the product is not adulterated. The product disposition would be made as part of the establishment's corrective actions under 9 CFR 417.3 or 416.15.

Establishments have been using prerequisite programs before in their processing operations, and the Agency has recently included the use of prerequisite programs as an option in another policy document. However, giving the establishment the option to include the antimicrobial agent or process in a prerequisite program in this rule is the first time prerequisite programs are recognized in codified regulations.

An establishment with products in Alternative 1 must have a post-lethality treatment that effectively reduces or eliminates *L. monocytogenes*, and an antimicrobial agent or process that suppresses any growth of the pathogen and extends the effect of the post-lethality treatment during the shelf life of the product. The Agency considers these treatments to be effective in controlling the pathogen resulting in a safe RTE product. If an establishment has an effective Sanitation SOP, any post-lethality contamination by *L. monocytogenes* would be very low, so the post-lethality treatment and the antimicrobial will be able to reduce or eliminate this contamination. If there is gross contamination, the effectiveness of the treatments may be reduced or negated. Therefore the Agency is relying on the establishment's Sanitation SOP to prevent contamination with *L.*

monocytogenes, and the post-lethality treatment and antimicrobials to further reduce or eliminate or suppress the pathogen.

Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. However, testing is recommended. Testing food contact surfaces in Alternative 1 could be minimal and primarily serve as a means to verify that the sanitary conditions in the establishment will not overwhelm the post-lethality treatment. A positive test on a food contact surface should trigger the establishment to review its sanitation program and post-lethality treatment to ensure that the treatment was properly applied for the product that came into contact with the positive. Furthermore, the establishment may determine that it is appropriate to conduct a product test after the post-lethality treatment to provide additional assurance that the treatment was effective. The establishments may test food contact surfaces for *L. monocytogenes*, or its indicator organisms, *Listeria* spp. or *Listeria-like* organisms periodically, to verify that their Sanitation SOP is effective. *L. monocytogenes* belongs to the *Listeria* genus or group and specie (sp.) *monocytogenes*. The genus *Listeria* includes other species (spp.) in addition to *monocytogenes*. Therefore a positive test for *Listeria* spp. or *Listeria-like* organisms would indicate the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator organisms for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen, although they could provide a measure of general sanitation. Guidelines on sanitation procedures and food contact surface testing for *L. monocytogenes* or its indicator organisms, *Listeria* spp. or *Listeria-like* organisms, are found in section G-VII-3.

2. Alternative 2

An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment or an antimicrobial agent or process that controls the growth of *L. monocytogenes*. Post-lethality treatments and antimicrobial agents and processes discussed above in the section on Alternative 1 can be used for Alternative 2. If an establishment uses a post-lethality treatment, it must have the post-lethality treatment in its HACCP plan and the treatment must be validated according to 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes* specifying the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment should be verified by testing the finished product for *L. monocytogenes*, and the verification results should be made available to FSIS personnel upon request. FSIS expects the establishment to conduct on-going verification of the CCP as detailed in its HACCP plan. The sanitary conditions likely will have a direct bearing on whether or not the post-lethality treatment is effective. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control *L. monocytogenes* in its product, it is not required to test food contact surfaces in the post-lethality environment, although it is recommended. However, FSIS most likely will conduct verification testing less frequently if the establishment tests food contact surfaces for *L. monocytogenes*, or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms).

Under Alternative 2, an establishment that only uses an antimicrobial agent or process to control *L. monocytogenes* in its product must have the agent or process included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment should have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time in days that the antimicrobial is effective. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. The Agency expects that the use of post-lethality treatments or antimicrobial agents and processes, will prevent a significant increase in numbers of organisms during the product's shelf life to levels resulting in a public health hazard.

If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment should document its antimicrobial agent or process, its implementation and its verification results sufficiently in order to show that the HACCP plan is adequate in controlling the pathogen. The establishment must verify that the antimicrobials are effective by testing for *L. monocytogenes* and have the verification results whether from carrying out its HACCP plan, or Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel.

If an establishment produces a product under Alternative 2 by using an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* in its product, it should maintain sanitation in the post-lethality environment in accordance with part 9 CFR 416. The sanitation program must include testing for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms). Studies on antimicrobials showed growth inhibition of *L. monocytogenes* if present at low levels of contamination during the shelf life of the RTE product. Antimicrobials were not shown to be effective at higher levels of contamination, so an effective sanitation program, which includes verification testing for food contact surfaces, should be implemented at the same time that antimicrobials are used.

The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. It must include the frequency of testing and identify the size and location of the sample sites to be sampled. It must include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its indicator organisms is maintained. In addition, the establishment must identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms. The product produced with an antimicrobial agent or process will be subject to more frequent FSIS verification testing compared to a product using a post-lethality treatment to eliminate *L. monocytogenes*.

3. Alternative 3

Under Alternative 3, the establishment does not apply a post-lethality treatment or an antimicrobial agent or process to control the growth of *L. monocytogenes* in the post-lethality exposed product. An establishment producing this type of product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment's HACCP plan, Sanitation SOP or prerequisite program. Because the establishment is not relying upon a post-lethality treatment or an antimicrobial agent or process to control *L. monocytogenes*, the product will be subject to frequent FSIS verification testing compared to the other alternatives. Examples of products in this alternative are fully cooked meat and poultry that are packaged and refrigerated such as hotdogs, deli meats, chicken nuggets, or chicken patties that did not receive any post-lethality treatment or antimicrobial agent or process.

For this alternative, the establishment must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. The

testing program should include the frequency of testing, identify the size and location of the sample sites and include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its indicator organisms is maintained. In addition, the establishment should identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms on a food contact surface. Recommended testing frequencies are discussed in the Sanitation section G VII-1.

Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or its indicator organisms on a food contact surface in the post-lethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The effectiveness of the corrective action can be verified by follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary. During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the sanitation problem indicated by the test result. If the food contact surface is positive for *L. monocytogenes*, the affected product lot (product that had direct contact with the food contact surface) would be considered adulterated. Affected product (product or food contact surface tested positive for *L. monocytogenes*) must be recalled, if in commerce, and destroyed or reworked with a process that is destructive of *L. monocytogenes*. If the food contact surface is positive for *Listeria* spp. or *Listeria*-like organisms (indicator organisms), the affected products are not considered adulterated. Establishments may move production from an affected line provided the new production line does not include the food contact surfaces that tested positive for *L. monocytogenes* and the new food and non-food contact surface areas are tested.

In order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes* from the positive food contact surface, the establishment must sample and test the lots for *L. monocytogenes* or its indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The ICMSF (International Commission on Microbiological Specifications for Foods) statistical sampling plan is an example of a plan that some establishments have used (Attachment 5).

If the held product tests positive for *L. monocytogenes*, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment must destroy the held product, or rework the held product using a process that is destructive of *L. monocytogenes*. The establishment must document the results of the testing and the disposition of the product. An example of a hold-and test scenario can be found in section G-VII-4 or in Attachment 6.

Products and the processing environment under Alternative 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment in Alternative 1 or 2. This is because the products in Alternatives 1 and 2 are formulated and/or processed to reduce or eliminate *L. monocytogenes* or limit its growth in the RTE product and present a lower risk than products in Alternative 3 that do not have these interventions. Likewise, an establishment in Alternative 3 that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for *L. monocytogenes* contamination in the FDA/FSIS risk assessment.

In determining the frequency of verification sampling, the Agency is expected to take into consideration the level of pathogen reduction achieved by the post-lethality treatment, the growth inhibition achieved by the antimicrobial agent or process during the shelf life of the product, and the rigor of the sanitation and testing program, i.e., whether the sanitation and testing program exceeds the compliance guidelines.

Products considered as deli and hotdog

*Like all RTE products exposed to the processing environment, deli and hot dog products that are exposed to the post-processing environment are subject to this rule. If the RTE product is not exposed to the post-processing environment, it is not subject to this rule. Depending on the method that an establishment chooses to control *L. monocytogenes* contamination in its processing, deli and hot dog products may be in Alternative 1, 2, or 3.*

Deli and hotdog products that receive a post-lethality treatment and antimicrobial agent or process fall under Alternative 1. An example is a hotdog that includes lactates or diacetates in the formulation and is steam pasteurized after repackaging.

*Deli and hotdog products with antimicrobial agents such as lactates or diacetates added in the formulation, but with no post-process lethality treatment would fall under Alternative 2. Another example of an Alternative 2 product is a hotdog product that received only a post-lethality treatment such as being packaged in casings with an antimicrobial agent that reduces the level of *L. monocytogenes*. If an establishment does not use a post-lethality treatment or an antimicrobial agent or process in the processing of deli and hotdog products, these products would fall under Alternative 3.*

Deli salads are also RTE post-lethality exposed, so they are covered by the rule. Deli meats that are used in salads receive additional handling after they are removed from their packages, and are mixed with other ingredients, thus exposing them to cross-contamination. An establishment producing deli salads with the meat and poultry components

that receive a post-lethality treatment or antimicrobial agent needs to have supporting documentation showing that the antimicrobial action is sufficient to control *L. monocytogenes* in all the salad ingredients if they choose to have their product in Alternative 1 or 2. A deli salad with a final pH below 4.39 in all ingredients of the salad, (e.g. due to the salad dressing or other ingredients added) would fall under Alternative 2, using an antimicrobial agent.

A cook-in-bag product such as cooked ham or poultry roll that is shipped intact in its cooking bag is not covered by the rule. If the cook-in-bag product sold to a deli is not removed from the bag in the deli but sold to the consumer in the original cooking bag, then it is not considered post-lethality exposed, and therefore is not covered by the *Listeria* rule. It is also not considered a deli product because simply selling a product in a deli does not result in a product that is defined in 9 CFR 430 as a deli product. However, if it is sold to a deli where it will be sliced and served in a sandwich or sold to the consumer, it is considered as a deli product.

Cooked chicken filets that are sliced or cut in strips, and frozen are covered under the rule since they are post-lethality exposed when sliced or cut. If these frozen products are shipped frozen, they fall under Alternative 2, using an antimicrobial process. If these products were refrigerated and shipped refrigerated, these will fall in Alternative 3.

C. Enhanced Level of Effectiveness of the Post-Lethality Treatment and the Antimicrobial Agent or Process

Products that receive a post lethality treatment achieving at least 2.0 log reduction of *L. monocytogenes* may likely be sampled less frequently by FSIS than products that receive a post-lethality treatment achieving <2.0 log reduction. Post lethality treatment achieving <1.0 log reduction will likely not be considered a post-lethality treatment for Alternatives 1 and 2 for purposes of the rule nor likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes* without supporting documentation that demonstrates this level of reduction provides a sufficient safety margin. In this case, the product will be viewed by the Agency as produced under Alternative 2 or 3, depending on whether the establishment uses an antimicrobial agent or process in addition to the post-lethality treatment

Likewise products receiving an antimicrobial agent or process that suppresses growth of *L. monocytogenes* such that there is 1.0 log or less increase during its shelf life may be expected to be sampled less frequently than products receiving an antimicrobial agent or process that allows the growth of *L. monocytogenes* by greater than 1.0 log increase during its shelf life. Use of an antimicrobial agent or process that allows more than 2.0 log growth increase during shelf life may not likely be considered an antimicrobial agent

or process for Alternatives 1 and 2 for purposes of this rule unless there is supporting documentation that demonstrates that this level of growth provides a sufficient safety margin. In such cases, the product may be moved to a higher risk Alternative. In addition, products that allow greater than 1.0 log growth of the pathogen during its shelf life will not likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes*. In this case, the product may also be moved to a higher risk Alternative.

The chart below shows examples of levels of control that establishments could achieve with regards to post-lethality treatment and antimicrobial agent or process for Alternatives 1 and 2. Establishments should use these levels to base their minimum verification measures in determining the effectiveness of their controls.

Expected Levels of Control for Post-lethality Treatments and Antimicrobial Agents or Processes

	Levels of reduction or inhibition achieved to control <i>L. monocytogenes</i>		
	Higher Level ¹	Lower level ²	Not Eligible ³
Post-lethality Treatment (log ₁₀ reduction of <i>L. monocytogenes</i>)	=> 2 (equal to or greater than 2)	<2 (less than 2)	< 1 (less than 1)
Antimicrobial Agent or Processes (log ₁₀ allowed increase of <i>L. monocytogenes</i>)	<= 1 (less than or equal to 1)	>1 (greater than 1)	> 2 (greater than 2)

¹Relatively less sampling by FSIS

²Relatively more sampling by FSIS

³Unless there is supporting documentation

D. Labeling

Antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products must to be listed in the ingredients statement of the product label. In addition, establishments that use a post-lethality treatment or an antimicrobial validated to effectively eliminate or reduce *L. monocytogenes*, or suppress or limit its growth in the product, can make claims or special statements on the labels of their products regarding the presence and purpose of use of the substances. The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims. An example of a statement that can be made is: "Potassium lactate added to prevent the growth of *L. monocytogenes*." All labeling claims and label changes to add such claims

must be submitted for evaluation and approval to the FSIS Labeling and Consumer Protection Staff.

Labeling Issues

Generic label approval and the new use of approved or listed safe and suitable antimicrobial agents. An establishment does not need to submit a label to the Agency for evaluation and approval when it adds an antimicrobial agent (e.g., sodium diacetate) that is approved or listed by FDA and FSIS as safe and suitable to a product formulation, provided the label can be approved in accordance with the generic labeling regulations in 9 CFR 317.5 and 381.133, (i.e., the product must have a standard of identity in Title 9 of the Code of Federal Regulations (CFR) or the Food standards and Labeling Policy Book and the labeling must not bear special claims, guarantees, or foreign language). All ingredients including antimicrobial agents require declaration on the label. Establishments may submit for temporary approval to use existing stocks of labels with revised formulations (up to six months) in order to update and produce new labels.

Approval of labels bearing claims. As with all claims on labels, if there is a labeling claim about the use of antimicrobial agents or lethality treatments, the labels must be submitted to the Agency for evaluation and approval before use. Documents for validation of the effectiveness of the post-lethality treatment or antimicrobial agent must be included with the label application. An establishment cannot put labeling claims of enhanced protection on RTE products that are not post-lethality exposed, such as cook-in-bag that are opened only by the consumer, because these are not covered by the Listeria rule.

Antimicrobial agents in comminuted beef products. The standard of identity for ground beef, chopped beef, and their cooked versions, does not provide for the addition of ingredients with the exception of non-fluid condimental seasonings, e.g., salt, pepper. Therefore, these products cannot be formulated with or treated with antimicrobial agents that are classified as having a lasting technical effect, e.g., sodium lactate and sodium diacetate, unless these products are descriptively labeled to reflect the use of the antimicrobial agents. For example, if sodium lactate was added, the product name on the label should be "Ground Beef with Sodium Lactate".

However, for beef patties, which are standardized products, the regulations permit the addition of ingredients such as, antimicrobial agents. Therefore, comminuted beef products formulated with antimicrobial agents and other approved or listed safe and suitable food ingredients can be labeled as "beef patties" and can be generically approved if the labeling does not bear any special claims, guarantees or

foreign language.

The labeling for other products with standards of identity that permit the addition of antimicrobial agents, e.g., luncheon meats, hotdogs, cooked whole muscle cuts (such as roast beef), may be approved in accordance with the regulations on generic label approval to reflect the addition of new, approved safe and suitable antimicrobial agents on labeling. The addition applies provided that no special claims or guarantees, foreign language, appear on such labels, per the generic labeling regulations.

Reclassification of products that are RTE as NRTE

Some products are expected to be lethality treated and RTE as shipped, as a matter of their common or usual identity, e.g., pates. Other products are defined by a standard of identity as RTE, that is, cooked, e.g., hotdogs. Some products are RTE based on labeling features, including Nutrition Facts, which declare nutrients in a product on a ready to serve or ready to eat basis. When these factors do not prevail, manufacturers may decide to reclassify products that have long been marketed as RTE products to NRTE products by doing the following:

(1) decide on the HACCP category that best fits their product based on the processing operations that are involved. In the situation where a product has been produced as a RTE product and it is not a product that is defined by common or usual identity (e.g., pepperoni) or standard of identity (e.g., hotdog) as a lethality-treated (e.g., cooked/fermented/dried) product, the manufacturer can re-characterize their product in terms of HACCP category. The manufacturer would need to ensure that documentation exists to support the HACCP category selected by the establishment for the product and that the appropriate category is reflected in the HACCP plan and labeling records;

(2) generate data that validate the cooking instructions that must appear on the labeling of NRTE products (and include in all the alternative methods of cooking temperature that the product must reach, i.e., 160°F) to ensure that consumers provide the lethality step. When the product has historically been viewed by the consumers as a "heat and eat" type of product, it is especially important for the establishment to make the distinction between the RTE product and the NRTE product. In addition, the "cooking instructions" should not be the same "heating" instructions that were previously used on labeling for the RTE products. Cooking instructions would need to include the internal

temperature to which the product is expected to reach for the consumer to eat the product safely.

(3) assess the label to ensure that it adequately reflects the features that are necessary on the principal display panel to convey that the product is a ready to cook product, e.g., "cook and serve," "cook and eat," "cook thoroughly," as well as safe handling instructions. The basis for the Nutrition Facts declarations, e.g., serving size, must be on a ready-to-cook basis, not on a ready-to-serve basis (the company has to establish a ready- to-cook basis for serving size if the regulations do not provide one).

(4) consider whether the label for the product can be approved consistent with the regulations on generic label approval (i.e., it is a label for a standardized product and that bears no claims, special statements, guarantees, or foreign language) -- such labels would not need to be sent to the Agency to be evaluated and approved prior to use.

If a meat or poultry product that is processed to a time/temperature that traditionally is considered to attain a full cook but the intended use of the product is such that the product is intended to receive a lethality treatment by the consumer, the product does not have to be labeled as RTE unless the product is defined by a standard of identify as a RTE product (e.g., hot dogs, franks, pork with barbecue sauce, etc.). Such product may be identified as a NRTE product provided that the labeling and validated cooking instructions are adequate to discern that the product must be cooked for safety by the purchaser. An example of such product is a cooked thick-sliced, center-cut ham slice on which the labeling indicates that the product is ready to cook and for safety the product must be cooked to attain a minimum temperature.

On the other hand, a thin sliced ham product in case-ready packaging states that the product is ready-to-eat without additional cooking and which would not be required to bear preparation/cooking instructions. Both products may have been processed in the same manner in the Federal establishment but handled differently regarding controls for L. monocytogenes.

Furthermore, some establishments also add a "cooking" statement on the label on a fully cooked, RTE product for consumers to cook to a specific temperature. In this case, the establishment is adding heating rather than cooking instructions on the label in order to specify the

temperature to which the product must be heated for palatability. In this case, the establishment does not need to have cooking instructions that have been validated to eliminate or reduce pathogens, nor does it need safe handling instructions on the label and the other requirements mentioned above.

E. Production Information Collection

An establishment that produces post-lethality exposed RTE products shall provide FSIS with estimates of annual production volume and related information for the types of meat and poultry products processed under Alternatives 1, 2, or 3 (9 CFR 430.4(d)). The establishment needs to provide the information at least annually, or more often, as determined by the Administrator. The Agency regards production volume as a more important risk factor than establishment size and therefore needs these data so that it can target its resources on higher volume operations in its verification program. FSIS will develop sampling frequencies for the establishments and the products based on these data. When sufficient data have been gathered (at least a year from implementation of the rule), the Agency expects to have the sampling frequency available to the establishments so that they will have an indication of how the risk of *L. monocytogenes* is tied to verification sampling.

The form by which to collect the data will be available to establishments in paper and electronic formats. An electronic form for this purpose will be available to the establishments at all times after the rule becomes effective. A draft sample form for the Production Information on Post-Lethality Exposed Ready-to-Eat Products collection can be found in Attachment 3.

F. New Technology Review

FSIS believes that the facilitation of the use of new technology represents an important means of improving the safety of meat, poultry and egg products. The Agency defines “new technology” as new, or new applications of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry, and processing of meat, poultry and egg products. The Agency has an interest in new technology if new technology could affect product safety, inspection procedures, or inspection program personnel safety, or if it would require a waiver of a regulation. Substances used as new technology must also meet the requirements for safety and suitability under the Agency’s food ingredient approval process. While FDA has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat and poultry products.

The FSIS New Technology Staff reviews new technology that can be applied in meat, poultry, and egg processing and inspection to facilitate the introduction of the new technology in establishment or plant operations. New technology for use on post-lethality RTE meat and poultry products to control the growth of *L. monocytogenes* should be sent to this office for review. FSIS issued the document on “Guidance Procedures for

Notification and Protocol Submission of New Technology” (www.fsis.usda.gov/OPPDE/op/technology/guidance.pdf) to aid in the submission of application for review of new technology.

G. Sanitation Guidelines for *Listeria monocytogenes*

Control of *L. monocytogenes* is a challenge to a processing plant’s sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come into contact with raw or finished product, establish a niche and form biofilms. The sanitation program should include cleaning and sanitizing procedures that have been proven effective for the particular operation, separation of raw and RTE processing areas, traffic control, employee hygiene, and equipment flow and design among others.

Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing were effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOPs). Sanitation SOPs could be viewed as the first step to designing a total system, including the HACCP plan that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant environment. The Sanitation SOPs as described in 9 CFR 416.12 through 416.16, give detailed requirements for developing and implementing the sanitation program, while 9 CFR 416.17 describes how FSIS will verify that each establishment is meeting the Sanitation SOP regulations. In brief, the regulations require the following:

- **Development of Sanitation SOPs (416.12)** – Each establishment must develop a written Sanitation SOP that describes all sanitation procedures that will be performed each day, before and during operations, with specific frequencies of each procedure and the responsible person for each task. It must also describe the cleaning process for all food contact surfaces, utensils, and equipment used to process your product(s). This document must be signed and dated by either the person responsible for the overall sanitation operations or a higher level employee in the establishment once it is implemented, and when any changes are made to the Sanitation SOPs.
- **Implementation of SOPs (416.13)** – All preoperational procedures identified in the Sanitation SOP must be done daily, before processing operations start. Each procedure must be performed at the specified frequency and they must be monitored daily.
- **Maintenance of Sanitation SOPs (416.14)** – Each establishment must routinely determine if the written Sanitation SOP is still effective in preventing direct product contamination and adulteration. If the Sanitation SOP is determined not to be effective because of changes in equipment, utensils, facility, operations, or personnel, changes in the procedures must be made to reflect changes
- **Corrective Action (416.15)** – The appropriate corrective action(s) must be taken when it has been determined by FSIS or by an establishment employee that the written Sanitation SOP has failed to prevent direct product contamination or adulteration of product(s).

- **Recordkeeping Requirements (416.16)** – Daily records must be maintained that describe how the sanitation activities were implemented and monitored, and all corrective actions taken; these records must be initialed and dated. Both computer records and paper records are appropriate; however, additional controls may be needed to ensure the integrity of the electronic data.
- **Agency Verification (416.17)** – FSIS will verify the effectiveness and adequacy of the written Sanitation SOP's to ensure that they meet all of the regulatory requirements. This will be done by reviewing all records, direct observations, and microbial testing as deemed necessary.

In addition to the Sanitation SOP required by FSIS, the *Listeria* rule requires an additional sanitation program targeting *Listeria monocytogenes*.

I. General Cleaning and Sanitation Procedures

An example of equipment and processing room cleaning using eight steps is outlined below. Cleaning should be increased and intensified during periods of construction.

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly. Equipment may need to be cleaned and sanitized again after re-assembly.
2. Wash and rinse floor.
3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or “set soils”).
4. Clean and scrub equipment. Always use at least the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use. CAUTION: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
5. Rinse equipment (rinse in same direction as product flow).
6. Visually inspect equipment to identify minute pieces of meat and biological residues (repeat steps 3 and 4 if not clean visually or by testing such as with ATP bioluminescence).
7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than steam for *L. monocytogenes* control. If steam heating equipment in an oven or tarp, the target internal temperature is 160° F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm² pressure and 6- 16 liters/minute) can also be used.
8. Remove excess moisture. This can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible

cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used. If cross-contamination is suspected, repeat steps 4 – 7.

II. Determining the Effectiveness of Sanitation Standard Operating Procedures (Sanitation SOPs)

The establishment should determine if the cleaning and sanitizing procedures it uses are effective by visual examination or testing or both. Three examples of visual examination or visual examination and testing are described below.

1. Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation SOPs. It can only detect observable contamination.
 - a. Before the start of operation, visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria,.
 - b. Record the results of the visual inspection.
 - c. If any residue is noted, corrective action should be taken and recorded.
 - d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
 - e. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.
2. Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.
 - a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation. The ATP test is a rapid test and results are available immediately.
 - b. Record the results of the ATP test and visual inspection.
 - c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.
 - d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to

determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

3. Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, its value lies in the measurement of the level of contamination. The level of contamination may assist the establishment in determining the source of contamination and the effectiveness of the sanitation SOP.
 - a. Visually verify that no meat or product residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
 - b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces (e.g., push-button on/off switches for the conveyor belt), and the processing environment.
 - c. Record the results of the visual inspection.
 - d. If any residue is noted, corrective action should be taken and recorded.
 - e. Record the TPC when analysis is complete.
 - f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
 - g. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

III. Traffic Control

Controlling the movement of personnel and raw and finished products will help prevent cross-contamination of finished products by raw materials and personnel. The following are steps that can be taken for traffic control:

1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.
2. Control traffic into and within the RTE areas
 - a. If possible, use air locks between raw and RTE areas.
 - b. Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination.
 - c. If foot baths are used:
 - i) Wear rubber or other non-porous boots.
 - ii) Maintain them properly,

- iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment
 - (1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).
 - (2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. The accumulation of biological material adhering to the cleats inactivate (or reduce) the bioavailability of chlorine and make it less effective. Monitor and maintain its strength if used.
- iv) Use a minimum depth of 2 inches.
- d. Use foam disinfectant spray on floor for people or rolling stock entering the room.
- 3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.
 - a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.
 - b. Remove outer garments (e.g., smocks) when leaving RTE areas.
- 4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing/handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product.
- 5. Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their “dirty” equipment hands onto food contact surfaces. If not possible:
 - a. Consider the need to cease operations until a full cleaning and sanitizing is done, or,
 - b. Maintenance personnel must change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned/sanitized footwear in such areas.
- 6. Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing/handling and RTE processing in order prevent cross contamination of finished product.
- 7. Pallets can serve as a source of cross-contamination – pallets for raw materials should not be used in RTE areas or used for finished product.
- 8. Drains from the “dirty” or “raw” side should not be connected to those on the “clean” or “cooked” side.
- 9. *There are instances when small establishments cannot separate the raw and cooked areas, or separate employees handling raw and cooked products by operating time. In this case, the establishment should plan to process cooked products first, then do a complete clean-up (thorough cleaning and sanitizing) of the processing area, processing and maintenance equipment, and personnel, and then do the raw products. The establishment's Sanitation SOP and their GMP or prerequisite program should address employee hygiene and*

traffic control during operation to prevent cross contamination and insanitary conditions.

10. Eliminate standing water which can facilitate the spread of *L. monocytogenes* into other areas of the plant. Sanitizer boluses can be used to sanitize standing water on a continuing basis.

IV. Employee Hygiene

Employee hygiene should be the responsibility of both the individual and management. The employee should be responsible for preventing contamination of food products and the management should be responsible for ensuring the employee is properly trained and maintains good practices.

1. Employee responsibilities and actions should include:
 - a. Use a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
 - b. Wash hands before entering the work area, when leaving work area, and before handling product.
 - c. If gloves are worn:
 - i. Gloves that handle RTE product must be disposable.
 - ii. Dispose immediately and replace if anything other than product and food contact surface is touched.
 - iii. Dispose of gloves when leaving the processing line.
 - d. Remove outer clothing when leaving RTE areas.
 - e. Do not wear RTE clothing inside restrooms or cafeterias.
 - f. Do not store soiled garments in lockers.
 - g. Do not eat in the locker room or store food in lockers because food may attract insects and vermin.
 - h. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.
2. Management responsibilities should include:
 - a. Providing hand washing facilities at proper locations.
 - b. Ensuring the employee receives proper hygiene instruction before starting – use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems.
 - c. Developing a system for monitoring employee hygiene practices.
 - d. Developing a system for tracking the training, testing, and certification.
 - e. Retraining employees before placing back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits.

V. Sanitizers

Cleaning and sanitizing are vital to any effective sanitation program. Thorough cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both cleaning and sanitizing solutions. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products produced in the establishment. Rather than relying on a single sanitizer, rotating sanitizers will help prevent the development of microorganisms resistant to a particular sanitizer.

The concentration and application processes for all sanitizers approved for use in meat and poultry establishments are referenced in Title 21 Code of Federal Regulations (21 CFR), Part 178.1010. All cleaners and sanitizers commercially available should have at the minimum, the following information either on the label or available on a specification sheet that must accompany the product:

- ✓ Product Description
- ✓ To Use – Instructions on how to use the product
- ✓ Properties
- ✓ Safety Information

Additional information that is sometimes available includes:

- ✓ Benefits
- ✓ Quality Assurance Statements
- ✓ Effectiveness against *Listeria*.

Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer, also has commercially available color coded products that are easy to associate with a particular cleaning or sanitizing task.

Krysinski, L.J., (1992) evaluated the ability of chemical cleaning and sanitizing compounds to remove and/or inactivate surface adherent *Listeria monocytogenes* from stainless steel and plastic conveyor belts. With respect to the sanitizers, the study showed that resistance of attached cells followed in descending order: polyester/polyurethane, and stainless steel. For the stainless steel, all of the sanitizers were effective in inactivating the adherent *Listeria monocytogenes* except chlorine and iodophor. None of the biocides were effective in sanitizing the surface of the polyester/polyurethane. The most effective sanitizers in these evaluations were acidic quaternary ammonia, peracetic acid, and chlorine dioxide. The cleaning agents used were effective in removing the attached *Listeria monocytogenes* for the stainless steel but not effective when used on the polyester/polyurethane chips. When the cleaning agents were followed by a sanitizer, reductions in the microbial load were observed. The study concluded that generally, acidic quaternary ammonia, chlorine dioxide, and peracetic acid were the most effective biocides on attached *Listeria monocytogenes*, less effective were the mixed halogens and

acid anionics, and the least effective were chlorine, iodophors, and neutral quaternary ammonium compounds.

VI. Sources and Control of *Listeria monocytogenes* Contamination

Listeria monocytogenes may be introduced into the processing environment by construction (perhaps the single most important factor associated with outbreaks), the failure to control sanitation procedures, employee hygiene, movement of supplies and products, or other entry vectors (Mead, 1999; Perl, 2000). The bacterium may be brought in by incoming raw product, processing environment or by employees. It can be transferred from coolers, walls, floors, equipment and construction by direct or indirect contact with the product.

Dust generated by construction activities can move throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. A study by De Roin et al., (2003) showed that dust contaminated with L. monocytogenes, once in contact with meat surfaces can survive and grow. Construction or maintenance activities that can result in contamination with L. monocytogenes include removal of drains, removal of floor coatings, removal of a wall or ceiling that has absorbed moisture, movement of potentially contaminated materials through RTE areas or areas that directly connect with RTE processing areas, and exposure of areas typically not accessible for cleaning. Tompkin (2002) considers the potential of introduction of a new, more virulent strain of L. monocytogenes into the environment from an outside source or through disturbance of a harborage site (e.g., the process of replacing floor drains, walls or cooling units) as a greater concern.

The following are steps that should be taken to prevent contamination of product with *L. monocytogenes* after cooking:

1. Verify that cooking or other control measures will eliminate *L. monocytogenes*. Most meat products implicated in human listeriosis are contaminated with *L. monocytogenes* after these measures are applied. Undercooking product or other inadequately or improperly verified lethality treatments may introduce *L. monocytogenes* to food contact surfaces or the environment after cooking and before packaging.
2. Prevent contamination of food contact surfaces and prevent the formation and growth of *L. monocytogenes* in a niche, especially in areas after the lethality step. A niche is a harborage site within the plant that provides an ideal place for *L. monocytogenes* to establish and multiply. Factors involved in the formation of niches include equipment design, construction activities, operational conditions that move product debris into difficult to clean locations, mid-shift cleanup, high pressure during cleaning, and

product characteristics that require excessive rinsing. Certain strains can become established in a processing environment for months or years. *L. monocytogenes* can be spread from these sites and re-contaminate food or food contact surfaces between the lethality step and packaging.

Examples of reservoirs and harborages of <i>L. monocytogenes</i> in RTE processing environment

Drains Hollow rollers on conveyors On-off valves and switches Worn or cracked rubber seals around doors Vacuum/air pressure pumps, lines, hoses Cracked tubular rods on equipment Air filters Condensate from refrigeration unit Floors Standing water Open or gulley drains Ceilings and over head pipes Overhead rails and trolleys Chiller and passageway walls and doors Chiller shelving Roller guards Door handles Boots Ice makers Saturated insulation (wet or moldy) Trolley and forklifts Compressed air in-line air filters Trash cans Cracked hoses Wet, rusting or hollow framework Walls that are cracked, pitted, or covered with inadequately sealed surface panels Maintenance and cleaning tools Space between close fitting metal-to-plastic parts Space between close fitting metal-to-metal parts
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3. Examine routes taken by products from heat treatment, or other control steps to eliminate *L. monocytogenes*, to final packaging.

Typical sites that result in <i>L. monocytogenes</i> contamination

Filling or packaging equipment Solutions used in chilling food Peelers, slicers, shredders, blenders, brine chill, casing removal system, scales, or other equipment used after heating and before packaging Spiral or blast freezers
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Conveyors

Bins, tubs, or other containers used to hold food for further processing
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4. Frequently clean sites known to support *L. monocytogenes* using effective cleaning procedures. The following is a recommended frequency for cleaning and sanitizing processing equipment and the plant environment:
 - a. Daily
 - i. All processing equipment
 - ii. Floors and drains
 - iii. Waste containers
 - iv. Storage areas
 - b. Weekly
 - i. Walls
 - c. Weekly/monthly
 - i. Condensate drip
 - ii. Coolers
 - d. Semiannually
 - i. Freezers
5. Validate that the cleaning and sanitizing procedures are effective.
6. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
7. Implement a microbial sampling program to monitor and detect sources of *L. monocytogenes* in the environment. Environmental testing is more effective than product testing alone to monitor and detect *Listeria* in the environment. For positive test results, conduct intensified cleaning and other necessary corrective actions. Follow up with intensified and targeted testing of implicated sites.
8. Design a sampling scheme to locate a niche before *L. monocytogenes* becomes established.
 - a. Determine the physical area to sample. Use prior experience with processing conditions and observation of cleaning and sanitizing procedures and equipment to determine the most likely source of contamination. For example, the use of high water pressure during cleaning may embed *L. monocytogenes* into parts of the equipment that are hard to clean effectively. The cleaning and sanitizing procedures also should be monitored to assure that the established procedures are being followed. All surfaces of processing equipment should be sampled but with a bias toward those areas identified as possibly problematic.

- b. Take 10 samples per line, with a maximum of 50 samples. The samples should include both food contact and non-food contact surfaces.
- c. Review at least the last month of results to determine trends or to revise sampling scheme.
- d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for intensified cleaning. Contamination is usually line specific unless a vector in the system is present (e.g., an employee contaminates multiple sites; a common surface prior to splitting the lines is contaminated).

Equipment Design

Selecting the appropriate equipment (e.g., designs that facilitate cleaning and sanitizing, equipment that easily dismantled for cleaning, durability) enhances cleaning operations and helps to control *L. monocytogenes* in the plant environment. The following are recommended steps to take when selecting equipment:

1. If possible, develop a team (persons from Quality Assurance, Sanitation, Maintenance, and Production) to evaluate equipment before it is purchased or set specific requirements for plant equipment. The equipment should be easy to clean and sanitize and not have potential *L. monocytogenes* harborage sites, such as hollow rollers.
2. Have the equipment reviewed by a third-party expert if possible.
3. Select equipment designed to minimize sites on the exterior or interior where *L. monocytogenes* can grow.
4. Select equipment designed to enhance cleaning.
 - a. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.
 - i. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.
 - ii. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.
 - iii. Select food contact surfaces that are inert, smooth and non-porous.
 - b. Equipment should be self-draining or self-emptying.

5. Equipment evaluation

- a. Thoroughly clean and sanitize equipment prior to using in production. Pathogens can live on surfaces that appear visually clean.
- b. Operate the equipment for 90 days, then,
- c. Disassemble to normal daily level, then
- d. Evaluate visually and microbiologically as the equipment is completely disassembled.

6. Maintain equipment and machinery by adopting regular maintenance schedules.

- a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.
 - i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
 - ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.
- b. If compressed air is used, maintain and replace in-line filters regularly.
- c. Use lubricants that contain listericidal additives such as sodium benzoate. *L. monocytogenes* can grow in lubricants that are contaminated with food particles.
- e. Use the appropriate cleaners and sanitizers on surfaces or equipment.

7. Control the Environment During Construction

*If possible, suspend operations during construction.
Otherwise:*

- a. *Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended **during and after** these disruptive events.*
- b. *Establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant.*
- c. *Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.*
- d. *Cover any construction debris when moving out of the construction area.*
- e. *Do not move debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.*
- f. *Schedule construction during non-processing hours.*

g. Conduct intensified cleaning and monitoring of food contact and environmental surfaces.

8. Control the Environment After Construction

- a. Schedule removal of all construction equipment, barriers, and final debris after production hours.*
- b. Perform a thorough clean-up and increased sanitation sampling at pre-operation inspection.*
- c. Continue intensified cleaning and monitoring of food contact and environmental surfaces until 3 consecutive negative tests on the food contact surfaces for 3 consecutive days.*

VII. Verifying the Effectiveness of the Sanitation Program

Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes a) recommended testing of food contact surfaces to verify the effectiveness of the sanitation program for each alternative from 9 CFR 430, b) a guide to testing for *Listeria* spp. or *Listeria*-like organisms, c) an example of a hold-and-test scenario, and d) an example of a Sentinel Site Program.

1. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. Sampling is required for Alternatives 2 (using antimicrobial agents or processes only) and 3, and recommended for Alternative 1. The sampling frequencies increase from Alternative 1 to Alternative 3 because the control program for *L. monocytogenes* decreases in intensity and effectiveness from Alternative 1 to 3. These frequencies should be increased if there is construction, change in the HACCP plan, roof leaks, or other events that could change or increase the probability of product contamination. Samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur. Establishments can also develop their own sampling plan based on their operations, or have a processing authority develop a sampling plan.

Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like or similar surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination.

The establishment is encouraged to hold all products being tested until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

- a. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.
 - i. Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent and process are expected to reduce and inhibit the growth of *L. monocytogenes* in the product.
 - ii. Sample at least 1 square foot area for each surface, if possible.
 - iii. Record the test results.
 - iv. If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:
 - (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
 - (2) *If the FCS test is positive for L. monocytogenes, the product in the sampled lot that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing L. monocytogenes, and documented in the establishment's HACCP plan.*
 - (3) Record the corrective actions taken.
 - (4) Retest the food contact surface.
 - (5) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.
 - (6) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.
- b. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of *L. monocytogenes*.
 - i. If a post-lethality treatment is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.
 - (1) Sample at least 1 square foot area for each surface, if possible.

- (2) Record the test results.
- (3) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:
 - (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
 - (b) *If the FCS test is positive for L. monocytogenes, the product that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing L. monocytogenes, and documented in the establishment's HACCP plan.*
 - (c) Record the corrective actions taken.
 - (d) Retest the food contact surface.
 - (e) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
 - (f) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.
- ii. If an antimicrobial agent is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. (Sampling is required in this case).
 - (1) Sample at least 1 square foot area for each surface, if possible
 - (2) Record the test results.
 - (3) Each time a FCS test positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
 - (4) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
 - (5) If 3 consecutive tests of food contact surfaces are positive for *Listeria* spp. or *Listeria*-like organisms:
 - (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
 - (b) Record the corrective actions taken.
 - (c) Hold the product.
 - (d) Test product for *L. monocytogenes*.
 - (e) Retest the food contact surface.

- (f) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
 - (g) If the test results for the product are positive for *L. monocytogenes*,
 - (i) Recall the product, if already shipped, and
 - (ii) Destroy the product, or
 - (iii) Re-work the product with a process that is destructive of *L. monocytogenes*.
- c. Alternative 3 – Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*. (Sampling is required in this case)
 - i. For establishments that produce non-deli or non-hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted once a month for large, small or very small volume establishments.
 - ii. For establishments producing deli and hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments.

FSIS regards production volume as a more important risk factor than establishment's size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break point between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey.
 - iii. Sample at least 1 square foot area for each surface, if possible.
 - iv. Record the test results.
 - v. If the first test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP or prerequisite program) and record.
 - vi. If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
 - vii. Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
 - viii. For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., *Listeria*-like organisms:
 - (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
 - (2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.

- (3) Record the corrective actions taken.
- (4) Hold the product (see hold-and-test scenario below and in Attachment 6).
- (5) Test product for *L. monocytogenes* at a rate that provides a level of statistical confidence that the product is not adulterated.
- (6) Conduct follow-up test of the food contact surface each day until the test result is negative for *Listeria* spp., *Listeria-like* organisms.
- (7) At the same time, continue to hold each day's production lot until the test results for the food contact surfaces are negative.
- (8) If the test results for the product are positive for *L. monocytogenes*,
 - (a) Destroy the product, or
 - (b) Re-work the product with a process that is destructive to *L. monocytogenes*.
- ix. For establishments producing products other than hotdogs or deli meats, if the third consecutive test of food contact surfaces is positive for *Listeria* spp., or *Listeria-like* organism (sampling is required in this case):
 - (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
 - (b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
 - (c) Record the corrective actions taken.
 - (d) Hold the product.
 - (e) Test product for *L. monocytogenes*.
 - (f) Retest the food contact surface.
 - (g) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria-like* organisms.
 - (h) If the test results for the product are positive for *L. monocytogenes*,
 - (i) Destroy the product, or
 - (ii) Re-work the product with a process that is destructive of *L. monocytogenes*.

For repeated FCS positives, the establishment should also conduct a comprehensive investigation to determine the cause and source of the contamination. This establishment should:

- a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.
- b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures.
- c. Locate niches
 - i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for *L. monocytogenes*
 - ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination

- d. Thoroughly clean and sanitize the individual parts.
 - i. Intense scrubbing is necessary to breakup or dislodge a biofilm.
 - ii. A change of cleaning or sanitizing solutions may be indicated.
 - iii. Fogging of the equipment or room with a sanitizer such as quaternary ammonium compounds could be used if problems persist.
- e. Reassemble and test again during operation until the FCS test negative on consecutive tests.

At the same time as the comprehensive investigation, the establishment should examine and review its HACCP plan, Sanitation SOP or its prerequisite program where the sanitation and testing programs are included, evaluate and determine if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of verifying that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

2. Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3

The chart below shows the frequencies of testing food contact surfaces that establishments in Alternatives 1, 2 and 3 should conduct for verification of the effectiveness of their sanitation program. Establishments should consider these frequencies when determining the level of *Listeria* control they believe is prudent in their establishments based on their operation and historical data. Those establishments assuming these levels of verification testing likely would be subject to more intense verification activity by FSIS, and their vulnerability regarding the scope of a recall likely is increased in situations where product in commerce is linked to their establishment. The scope of a recall is dependent, in part, upon the level and type of documentation that establishment maintains on the on-going effectiveness of their operation.

Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3.

	Food Contact Surface Testing	
	Higher Frequency	Lower Frequency
Alternative 1	> 2/year/line	2/year/line
Alternative 2	> 4/year/line	4/year/line
Alternative 3		
Non-deli, non-hotdogs	> 1/month/line	1/month/line
Deli, hotdogs:		
Very Small volume plant	> 1/month/line	1/month/line
Small volume plant	> 2/month/line	2/month/line
Large volume plant	> 4/month/line	4/month/line

3. Testing for *Listeria* spp. and *Listeria*-like Organisms for Food Contact Surfaces and Other Environmental Testing

Listeria spp. or *Listeria*-like organisms are the indicator organisms to be used for *L. monocytogenes* because their presence indicates the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator tests for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen. However, testing for these organisms can be conducted in addition to the testing for *L. monocytogenes* or its indicator organisms to monitor the effectiveness of the cleaning procedures and level of contamination during processing. Rapid screening methods for *Listeria* spp which takes hours are available. To verify effectiveness of cleaning and sanitizing, ATP testing for background levels is available, but this is not specific for *Listeria*.

FSIS microbiology laboratory methods are available and can be downloaded at

http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/

Any methodology used by a regulatory body or validated by a recognized body is acceptable. *In cases where the test method was sent for evaluation to a recognized body but has not been approved yet, the establishment may use the test method if it is equivalent or better in sensitivity to the FSIS method as determined by a scientifically designed process. In the absence of test methods that are validated or equivalent in sensitivity to FSIS methods, the establishment can use any method it chooses, but the establishment would assume greater risk for allowing adulterated product into the marketplace, subsequent voluntary recall requests and other regulatory actions. One consequence of using a non-recognized method is that FSIS may target the establishment for increased verification checks, including recordkeeping, observation of production, and testing by FSIS.*

a. *Listeria* spp. testing

- i) The methodology must employ enrichment prior to *Listeria* spp. screening.
- ii) *Listeria* spp. screening is conducted from the enrichment using an immunoassay, nucleic acid assay, or equivalent *Listeria* spp.-specific technology.
- iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. and/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.

b. *Listeria*-like organism testing

- i) The methodology must employ enrichment prior to *Listeria*-like organism screening.

- ii) The *Listeria-like* organism positive screening result may be indicated by the presence of suspect *Listeria* spp. Colonies after selective plating, or may be indicated by biochemical changes to screening broths (e.g., Fraser Broth) that are consistent with the potential presence of *Listeria* spp.
- iii) The above enrichment and screening must be part of a method in use by a government agency (i.e., FSIS or FDA) or validated by a recognized body (e.g., AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. And/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.
- iv) Aerobic plate counts, ATP assays and other indicator organism tests that do not specifically meet the above requirements may be employed by the establishment for supplemental sanitation testing. However, these tests do not meet the FSIS expectations for *Listeria* spp. or *Listeria-like* organism food contact and other environmental surface testing programs that may be conducted by the establishment.

4. Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3

*Assuming it takes to 3 days to obtain a test result for *Listeria* spp., or *Listeria-like* organisms:*

Day 1 – Take food contact surface (FCS) samples

*Day 4 –FCS sample (from Day 1) negative for *Listeria* spp. or *Listeria-like* organisms.*

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

*If FCS sample positive (from Day 1) for *Listeria* spp. or *Listeria-like* organisms.*

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Continue production.

*Day 7 – Follow-up FCS sample (from Day 4) is negative for *Listeria* spp. or *Listeria-like* organisms.*

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

*If follow-up FCS sample (from Day 4) is positive for *Listeria* spp., or *Listeria-like* organisms.*

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ *Hold and test Day 7 product lot (for L. monocytogenes or Listeria spp. or Listeria-like).*
- ✓ Continue production, hold product from the day's production

Day 8 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 9 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 10 –

If FCS sample (day 7 sample) is negative for Listeria spp., or Listeria-like organisms.

- ✓ Continue production and hold product from days 7, 8, 9 and 10 until the results from Day 7 product testing and Days 8, 9, 10 FCS testing are available and found negative, unless there is compelling justification that affected products are not adulterated.
- ✓ Resume FCS testing according to frequency stated in sanitation program

If FCS sample (day 7 sample) is positive for Listeria spp., or Listeria-like organisms:

- ✓ Hold and test product from day 10 production.
- ✓ *Test product from days 7, 8, 9, and 10 for L. monocytogenes, L. spp. or Listeria-like organisms*
- ✓ Take corrective action
- ✓ Intensive cleaning and sanitizing
- ✓ Take FCS sample-- target most likely source of contamination, and additional tests in surrounding FCS area

Day 14 – If Day 7 product is positive for *L. monocytogenes*, destroy product, or rework product with a process that is destructive of *L. monocytogenes*. Recall product if already in commerce.

If product is positive for *L. spp.*, verify that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions are not adulterated by testing to provide compelling justification.

If the establishment tests FCS samples for *L. monocytogenes*, and the FCS test positive for the pathogen, the sampled lot is considered adulterated.

Every time there is a second or more (consecutive) follow-up FCS positive, product is held and tested for *L. monocytogenes*. Only product lots implicated with a second or more (consecutive) follow-up FCS positive are held and tested. Every time there is a product positive for *L. monocytogenes*, product is held, and destroyed or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued.

Repeated FCS positives would imply a critical sanitation problem and the establishment needs to conduct intensive testing and intensive cleaning and sanitizing. At the same time the establishment should investigate the cause and source of the contamination and review the documents where the sanitation and testing programs are included to determine if there are design or execution flaws. The establishment should have provisions in their sanitation and testing program for these kinds of situations.

5. Sentinel Site Program Example

Some establishments have adopted a sentinel site program for the control of *L. monocytogenes* in RTE meat and poultry products. A sentinel site program is similar to traditional *Listeria* control programs – separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate *Listeria* when it is detected. The distinctive characteristic of this control program is that in the case of a positive *Listeria* test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur.

The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a food contact surface or non-food contact surface tests positive for *Listeria* spp. or *Listeria*-like organisms, testing is intensified in the identified area.

If a non-food contact surface sampling site is found to be positive for *Listeria* spp. or *Listeria*-like organisms during routine monitoring, intensified sampling is initiated as soon as possible. Under intensified sampling, three samples per day (one each at pre-op, 1st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for *Listeria* spp. or *Listeria*-like organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for *Listeria* spp. or *Listeria*-like organisms. Once nine consecutive samples are found negative, that site will be returned to routine sampling.

Similarly, the food contact surface site that initially tests positive for *Listeria* spp. or *Listeria*-like organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for *Listeria*, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP, since *Listeria* would, at that point be considered a hazard not reasonably likely to occur. The site testing positive for *Listeria* would be considered a suspect harborage for *L. monocytogenes* and corrective actions taken. Testing becomes the verification step.

Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, 1st shift, 2nd shift) be taken until nine consecutive samples are negative for **both** *Listeria*

spp. and *L. monocytogenes*. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both *Listeria* spp. and *L. monocytogenes*. All products that have contact with that particular site must be placed on hold pending test results.

If nine consecutive samples are negative for *Listeria* spp. and *L. monocytogenes*, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for *L. monocytogenes*. Any sites testing positive for *L. monocytogenes* would require testing of the product.

Sentinel Site Program Example Flowchart

1. Routine Environmental Sampling
 - a. 5 samples/line/week
 - i. 3 – food contact surface samples
 - ii. 2 – non-food contact surface samples
 - iii. *Listeria* spp.
2. Non-food Contact Surface Testing
 - a. If negative for *Listeria* spp., continue Routine Environmental Testing
 - b. If positive for *Listeria* spp., intensify sampling
 - i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
 - ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
 - iii. If any sample is positive, continue sampling 3 samples/site/day until 9 consecutive samples are negative
3. Food Contact Surface (FCS) Testing
 - a. If negative for *Listeria* spp., continue Routine Environmental Testing
 - b. If positive for *Listeria* spp., intensify sampling
 - i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
 - ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
 - iii. If any sample is positive, make sanitation for that site a CCP
4. CCP Testing
 - a. Collect 3 samples samples/site/day for 3 consecutive days for *Listeria* spp. **and** *L. monocytogenes* (9 consecutive samples)
 - b. If 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, return to Routine Environmental Sampling and eliminate the CCP
 - c. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*
 - i. Place product on hold
 - ii. Release product if site and production date have negative results for *L. monocytogenes*

- iii. Continue testing until 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, then return to Routine Environmental Sampling and eliminate the CCP
- d. If any sample is positive for *L. monocytogenes*, test the product for *L. monocytogenes*
 - i. Reprocess or destroy product testing positive for *L. monocytogenes*

H. PROJECTED RISK-BASED VERIFICATION TESTING PROGRAM

FSIS expects to begin this risk-based verification-type program after it has received production volume and related information from establishments operating in accordance with 9 CFR 430, sometime within the first year to 18 months after the effective date of October 6, 2003. For purposes of the verification testing program, FSIS is planning to group RTE products into at least four sampling projects for routine analysis:

- #1 – Prevalence Verification Testing
- #2 – RTE products in Alternative 1 under 9 CFR 430
- #3 – RTE products in Alternative 2 under 9 CFR 430
- #4 – RTE products in Alternative 3 under 9 CFR 430

Prevalence verification testing program. FSIS will direct Inspection Program Personnel to collect samples of any RTE product regardless of the control measures for pathogens, compliance history, production, volume, etc. All establishments, regardless of plant size, production volume, or process design will have an equal chance of being sampled each fiscal year in sampling frame #1. Note: All Ready-to-Eat products whether post-lethality exposed *or not* will be sampled in this prevalence category. The sampling projects that cover the alternatives according to 9 CFR 430, only apply to post-lethality exposed product.

Results from this project will be unbiased to the extent that production practices are not addressed as they are in the other RTE verification sampling projects. Overall prevalence of the pathogens, for which FSIS tests, in all types of operations can be ascertained. FSIS randomly collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern, namely, *Listeria monocytogenes*, *Salmonella* and *E. coli* O157:H7. Inspection program personnel will carry out HACCP, Sanitation SOPs, and prerequisite program verification activities, including the review of records and laboratory results, to verify that establishment's are properly addressing the control of pathogens.

Sampling Under Alternatives 1, 2, and 3 of 9 CFR 430. Until FSIS has actual production volume and associated data as a result of the information request contained within 9 CFR 430, and until FSIS has finished the risk assessment on verification sampling, FSIS will not use sampling frames #2, #3, and #4. In the meantime, FSIS will design the scheduling of sample requests using the risk priority list contained in FSIS Directive 10,240.4.

Follow-up Sampling. When a sample taken under the sampling projects outlined above is found to be positive for a pathogen, FSIS will conduct follow-up verification testing after the establishment has taken its corrective and preventive actions. The follow-up sampling will be conducted under the Intensified Verification projects, and may include direct product contact surface and non-product contact surface sampling in addition to the product sampling.

Intensified verification testing projects. These projects are designed for testing in any operation involving any meat or poultry product, regardless of the establishment's control procedures, the production volume, etc, due to the production of adulterated product (i.e., the pre-shipment review has been completed), investigative purposes (e.g., as a result of an outbreak of foodborne disease), or concern that the establishment may not be properly controlling for pathogens. The projects may include instructions to Inspection program personnel to collect multiple samples. Intensified verification testing will include:

1. Increased frequency and number of samples taken for product testing (as compared to targeted verification testing), and the collection of environmental samples.
2. Increased FSIS record verification checks regarding the design and implementation of the food safety system.

These sampling projects will be scheduled by OFO through OPHS on a case-by-case basis.

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ATTACHMENT 1

CONTROL REQUIREMENTS for *LISTERIA MONOCYTOGENES*

Requirements	→ Increasing Risk Levels and Verification Testing →				
	ALTERNATIVE 1	ALTERNATIVE 2		ALTERNATIVE 3	
	Post-lethality Treatment AND Antimicrobial agent or Process	Post-lethality Treatment OR Antimicrobial agent or Process	Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment	X	X			
Document effectiveness of antimicrobial agent or process	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS)			X	X	X
State testing frequency			X	X	X
Identify size and location of sites to be sampled			X	X	X
Explain why testing frequency is sufficient			X	X	X
Identify conditions for Hold-and-Test, when FCS (+)			X	X	X
Additional Sanitation Program Requirements					X
Follow-up testing to verify corrective actions are effective after 1 st FCS (+)					X
If follow-up testing yields 2 nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots for <i>L. monocytogenes</i> using sampling plan that provides statistical confidence. Release, rework or condemn products based on results. Document results and product disposition.					X

OTHER REQUIREMENTS

- Post-lethality treatments must be included in the HACCP plan.
- Antimicrobial agents must be included either in the HACCP plan, Sanitation SOP, or prerequisite program.

- Sanitation programs must be included either in HACCP plan, Sanitation SOP, or prerequisite program. If in the Sanitation SOPs or prerequisite program, there must be supporting documentation for the hazard analysis determination that this hazard is not reasonably likely to occur.
- Verification testing for sanitation in the post-lethality environment may be for *Listeria monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.
- Product testing must be confirmed for *Listeria monocytogenes*.
- Establishment must maintain sanitation in the post-lethality environment per 9 CFR 416.
- If *L. monocytogenes* controls are in HACCP plan, establishment must validate and verify effectiveness per 9 CFR 417.4
- If *L. monocytogenes* controls are in Sanitation SOPs, their effectiveness must be evaluated per 9 CFR 416.14.
- If *L. monocytogenes* controls are in prerequisite programs, the program and results must be included in documentation required by 9 CFR 417.5
- Establishment must make verification results available to inspection program personnel.

ATTACHMENT 2

CHART OF RTE VS NRTE PRODUCTS

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	<ul style="list-style-type: none"> Raw Product Ground – ISP 03B Raw Product Not Ground – ISP 03C Not Heat Treated Shelf Stable – ISP 03E Heat Treated –shelf stable – ISP 03F Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H Products with secondary inhibitors Not Shelf Stable – ISP 03I 	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	<ul style="list-style-type: none"> Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). <p>If it is not obvious that the product is raw and needs to be cooked:</p> <ul style="list-style-type: none"> Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” Validation that: <ol style="list-style-type: none"> Cooking and preparation instructions on the product are sufficient to destroy pathogens. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	<ul style="list-style-type: none"> Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H 	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	<ul style="list-style-type: none"> Validation that: <ol style="list-style-type: none"> The meat/poultry component received an adequate lethality treatment for pathogens. Cooking and preparation instructions on the product are sufficient to destroy pathogens. Instructions are realistic for the intended consumer. Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). <p>NOTE: Inspection program personnel are to collect samples as RTE</p>

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
				if the establishment does not follow the guidance above.
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	<ul style="list-style-type: none"> • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I 	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	<ul style="list-style-type: none"> • See part 417 of the meat and poultry regulations.

ATTACHMENT 3

PRODUCTION INFORMATION ON POST-LETHALITY

EXPOSED READY-TO-EAT PRODUCTS SAMPLE FORM (DRAFT)

[illegible]

STATEMENT OF WORK (SOW)

SECTION 1: PROJECT INFORMATION

Project Name: _____

Client: _____

Project Manager: _____

Start Date: _____

End Date: _____

SECTION 2: PROJECT SCOPE

Project Description: _____

Project Objectives: _____

Project Deliverables: _____

SECTION 3: PROJECT BUDGET

Project Budget: _____

Project Funding Source: _____

SECTION 4: PROJECT RISK

Project Risk: _____

Project Risk Mitigation: _____

SECTION 5: PROJECT SCHEDULE

Project Schedule: _____

Project Milestones: _____

SECTION 6: PROJECT TEAM

Project Team: _____

Project Roles: _____

SECTION 7: PROJECT COMMUNICATION

Project Communication: _____

Project Reporting: _____

SECTION 8: PROJECT CLOSURE

Project Closure: _____

Project Evaluation: _____

[illegible]



ATTACHMENT 4

STUDIES ON POST-LETHALITY TREATMENTS

and ANTIMICROBIAL AGENTS

A. Studies on Post-lethality Treatments

(Mention of trade marks or commercial names does not constitute endorsement by USDA)

I. Steam Pasteurization and Hot Water Pasteurization

Post processing contamination of RTE meat and poultry is mostly confined to the surface. Pasteurization by steam and hot water acts on the surface microbial contaminants by the action of heat. Studies on surface pasteurization using steam or hot water were shown to be effective in reducing this contamination.

Studies by Murphy et al. (2003a) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 7 log₁₀ reduction of *L. monocytogenes* in inoculated vacuum packaged fully cooked sliced chicken. The reduction was effective when single – packaged breast fillets, 227 g- package strips and 454 g-packaged strips were heat treated at 90 C in a continuous steam cooker or hot water cooker for 5, 25 and 35 minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during post-cook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using *L. innocua* and verified for *L. monocytogenes*.

II. Pre-Package Pasteurization and Post-Package Surface Pasteurization

Pre-package surface pasteurization treatment of fully cooked meat removed from their packaging wrap and inoculated with *L. monocytogenes* resulted in a 1.25 to 3.5 log reduction with a treatment time of 60-120 sec at 475 to 750° F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef, whole corned beef, and whole and formed ham using a radiant oven (“Infrared Grill”, Unitherm FoodSystems). Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9 log reduction for ham, 2.7-4.3 log reduction for bologna, or a 2.0-3.75 log reduction for roast beef. The level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time.

Muriana et al., (2002) used a stainless steel water bath (similar to the Unitherm commercial Aquaflo food processor) to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with *L.*

monocytogenes and vacuum packaged. Results show a 2-4 log decrease in the levels of *L. monocytogenes* in inoculated products post-cooked at 195-205° F for 2-10 min.

Treatment of processed foods with acidified sodium chloride (ASC) is another example of pre-packaging treatment. ASC is an antimicrobial agent that is approved for use on processed meat food products (unless precluded by standards of identity in 9 CFR 319) prior to packaging of the food for commercial purposes (21 CFR 173.325 (f)). It is applied as a dip or spray at levels that result in sodium chlorite concentration of 500 to 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9. It is approved as a secondary direct food additive, and considered as a processing aid, with very temporary or short term technical effect (bactericidal antimicrobial activity) after which it rapidly degrades to leave no long term residues or actives remaining (Kemp, Alcide Corp., personal communication, 2003). Because of this, it does not have to be included in the ingredient listing of the label. Marsden et al. (2000, unpublished), evaluated sodium chlorite (1,200 ppm) with 0.9% citric acid for its effectiveness in reducing *L. monocytogenes* on retail Little Smokies sausages. Results show that a water wash gave a 1.2 log cycle reduction of *L. monocytogenes*. An ASC dip for 15 sec provided a 1.0 log cycle reduction better compared to water wash. ASC exposure time of 30 sec gave 1.1 and 1.6 log cycle reductions over the water wash control, for spraying and dipping, respectively. Spray wash or dipping was found to be comparable in antibacterial effectiveness against *L. monocytogenes*.

III. High Hydrostatic Pressure Processing

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating *L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10^4 *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34° F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.

B. Studies on the Use of Antimicrobial Agents

I. Addition of Lactates, Acetates, Diacetates to Meat Formulations

Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed meat formulations are also known to potentially inhibit pathogenic bacteria

especially *L. monocytogenes*. These antimicrobials inhibit growth of pathogens by inhibiting their metabolic activities. Interest in these antimicrobials is in the growth inhibition of *L. monocytogenes* in post lethality exposed RTE meat and poultry products. Several studies used these antimicrobials to show their ability to inhibit growth of *L. monocytogenes* in different meat formulations.

Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of *L. monocytogenes* in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of *L. monocytogenes*. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with *L. monocytogenes* by applying to the surface of 100g of cured meat (four slices).

The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of *L. monocytogenes*, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. The investigators provided a final regression equation predicting the growth of *L. monocytogenes* in cured RTE meat products stored at 4° C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing with actual *L. monocytogenes* growth data from an independent challenge study conducted with four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of *L. monocytogenes* exceeded those of the observed values by about 24 %.

This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of *L. monocytogenes*. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form *Listeria* Control Model.

The Opti.Form Listeria Control Model (PURAC) is a unique tool to calculate the levels of lactate and diacetate required to retard the growth of *Listeria monocytogenes* in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al, 2002, above. The model, which is available on CD-Rom includes:

- instructions on how to use the model

- explanation on the development of the model
- information on the anti-microbial effect of lactate and diacetate
- lactates and diacetates and use of these products
- regulations and labeling
- literature references

To receive a free copy of the model on CD-Rom, call: 888-899 8229, E-mail pam@purac.com

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm² of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days. Results are as follows:

ANTIMICROBIAL	LEVEL (%)	<i>L. MONOCYTOGENES</i> GROWTH INHIBITION
Sodium lactate	3	70 days no pathogen growth
Sodium diacetate	0.25	50 days no pathogen growth
Sodium acetate	0.25, 0.50	20 days no pathogen growth
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	0.5	120 days no growth and reduced pathogen growth
Inoc. Control	0.0	Increased to 6 logs in 20 days

Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

No pathogen growth refers to zero increase in the number of inoculated *L. monocytogenes* cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH except for sodium diacetate at 0.5 % which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3 % sodium lactate in the frankfurter formulation and obtain no growth of *L. monocytogenes* up to 70 days at refrigerated storage of 4° C. If the lethality treatment is adequate to eliminate *L. monocytogenes*, then the only probable source of *L. monocytogenes* would be from exposure of the product during peeling and repackaging. However, the establishment's sanitation program may keep the numbers to a very low level, and 3 % sodium lactate included in the formulation would inhibit the growth of *L. monocytogenes* during the product's refrigerated shelf life. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hotwater treatment. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C shows:

<u>TREATMENT</u>	<u>LEVELS</u> (%)	<u>L. MONOCYTOGENES GROWTH</u> <u>INHIBITION</u>
Sodium lactate	1.8	35-50 days no growth
Sodium lactate + sodium acetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Sodium diacetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Glucuno-delta- lactone	1.8 0.25	120 days no growth, 35-50 days growth reduction
Hot water treatment (80° C, 60 s) + Sodium lactate	1.8	Inoc. population reduced by 0.4-0.9 log CFU/cm ² , and 50-70 days growth reduction by 1.1-1.4 CFU/ cm ²
Hot water treatment (80° C, 60 s)		Increase in growth to about 6-8 logs in 50 days
Inoculated Control, no treatment		Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days

Note: Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

Glass et al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with *L. monocytogenes* mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5° C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7° C for up to 84 days.

The surface treatment consisting of dipping wieners into solutions containing up to 6 % lactate and up to 3 % diacetate for 5 s did not delay pathogen growth, indicating that dipping wieners in the lactate/diacetate solutions is not an efficient way to apply the antimicrobials. However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of *L. monocytogenes*. Results are as follows:

<u>PRODUCT</u>	<u>Sodium</u> <u>Lactate</u> (%)	<u>Sodium</u> <u>diacetate</u> (%)	<u>L. monocytogenes</u> _levels (CFU/pkg)
Bratwurst uncured, unsmoked	3.4	0.1	Growth delayed for 4-12 weeks at 7 and 3°C storage, respectively.
	2.0	0.0	Growth delayed for 1-2 weeks at 7 and 3°C
Bratwurst	3.4	0.1	Growth inhibited for 12 weeks at 7 and

cured, smoked	0.0	0.0	3°C Growth up to 1 log after 4 weeks at 7 and 3° C
Wieners	3.0 1.0	0.0 0.1	Growth inhibited for 60 days at 4.5° C Growth inhibited for 60 days at 4.5° C

Study by (Porto et al., 2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3 % potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated with a mixture of *L. monocytogenes*. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10° C.

Results show that addition of 2 % or 3 % potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of *L. monocytogenes* during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH, and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria.

Potassium lactate (%)	Inoculum CFU/pkg	Storage temp °C)	Days Storage	<i>L. monocytogenes</i> levels (CFU/package)
2.0	20	4	90	Remained at about 1.6 log
3.0	20	4	90	Remained at about 1.4 log
3.0	500	4	90	Remained at about 2.4 log
0.0	20	4	90	Increased to about 4.6 log
0.0	500	4	90	Increased to about 5.0 log
2.0	20	10	60	Remained at about 1.4 log
3.0	20	10	60	Remained at about 1.1 log
0.0	20	10	60	Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days
3.0	500	10	60	Remained at about 2.4
0.0	500	20	60	Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days

II. Growth Inhibitor Packaging

Growth inhibitor packaging is an intervention, which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat/sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent *Listeria* contamination during subsequent peeling and packaging processes. Growth inhibitor packaging used in conjunction with functional HACCP and Good Manufacturing Practices provides the industry with one more tool in

their intervention strategy to control the risk of pathogen contamination in ready-to-eat meat and poultry products.

Studies on meat formulations for hot dogs using NOJAX[®] AL[™] (Viskase) showed that use of the casings provide a lethality hurdle to the growth of *Listeria monocytogenes*, not just an inhibitory effect. The lethality impact is delivered within the first hours/days of the sausage/hot dog package life. This impact is dependent on many variables but is generally in the range of 1 – 2 log kill of *L. monocytogenes* at high levels of inoculation. This performance has been observed in challenge studies conducted on hot dogs drawn from commercial full-scale trials at a number of commercial processing plants. In high inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and as expected, the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining *L. monocytogenes* begin to grow.

NOJAX AL is available in the U.S. having approval by both FDA and USDA for its key component, nisin. This GRAS component must be included in the ingredient statement via a label change request to the FSIS Labeling and Consumer Protection Staff. Because this is a naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90 days with a not to exceed 85° F.

This technology can be applied to most hot dogs and sausages that are encased in cellulose casing. This casing intervention can be used in any instance where casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and possibly natural casing. As part of a manufacturer's decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps, plant reconfigurations or introduction of process bottlenecks—essentially processor transparent in all aspects of use except casing storage requirements; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement.

Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hot dogs.

Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked ready-to-eat chicken against *L. monocytogenes*. Cooked chicken samples inoculated with *L. monocytogenes* were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1 % calcium propionate and stored at 4 C or 8 C for 24 days. After 16 d at 4 C, *L. monocytogenes* was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the study for controlling *L. monocytogenes* on the surface of ready-to-eat chicken was using edible zein film coatings containing nisin at a storage temperature of 4°C.

The use of film coatings in a processing plant would be to fully process the meat products then coat them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated.

This study has not been tested in commercial poultry processing conditions.

Some general observations from the published studies on antimicrobials:

- Lactates, acetates and diacetates were found more effective in inhibiting growth of *L. monocytogenes* when used in combination than when used singly.
- These antimicrobials were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products.
- When used in combination, the amount needed to inhibit growth may be reduced.
- These antimicrobials were found to have listeristatic activity more than listericidal activity, i.e. they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment's sanitation program should control gross contamination of the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy.
- Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials.
- The antimicrobial activity of lactates and diacetates when used singly or in combination is affected by the level of contamination of the meat product surface, and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere.
- Application of the treatments used in these studies is limited to the formulations, products and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore the effectiveness of the antimicrobials used in these studies must be verified by the establishment for other processed meat products and other storage temperatures.
- Antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product. Currently the targeted commercial shelf life of refrigerated cooked meat products in the U.S.A. is 75 to 90 days.
- Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials.
- These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite, or in products stored at strict refrigeration temperatures.
- Use of these antimicrobials may be a cost effective antilisterial method that very small establishments can use.

References are found on pp. 48-49.

ATTACHMENT 5

Hold-and-Test Sampling for the FSIS LM Rule

Background

On June 6, 2003, FSIS published an interim final rule on the control of *Listeria monocytogenes* in ready-to-eat (RTE) meat and poultry products. Most processors of RTE products will have to conduct microbiological testing of product contact surfaces. The rule states that establishments using antimicrobial agents or processes under Alternative 2 and establishments producing non-hotdog or non-deli products under Alternative 3 must identify the conditions under which they will implement hold-and-test procedures. The rule describes the hold-and-test procedures to be followed by establishments producing hotdog and deli products under Alternative 3. Under alternative 3, an establishment producing a hot dog or deli product that obtains a positive for *Listeria monocytogenes* or an indicator organism such as *Listeria* spp. in follow up testing on food contact surfaces must hold lots of product that may have become contaminated by the food contact surface and must sample and test these lots before release into commerce. In addition, establishments producing RTE products must identify conditions under which the establishment will implement hold-and-test procedures following a positive test for *Listeria* spp. or *L. monocytogenes* on a food contact surface.

In response to NFPA questions, FSIS officials have indicated that the intent is not to set a minimum level of sampling, but rather to rely on the industry to identify what they individually or as a group consider to be reasonable and scientifically supportable. The Agency encouraged the industry to consider the ICMSF tables (International Commission on Microbiological Specifications for Foods. *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. Kluwer Academic/Plenum Publishers, NY. 2002).

ICMSF Sampling Plans for *Listeria monocytogenes*

ICMSF categorizes microbial hazards according to risk – moderate, serious and severe. ICMSF ranks *L. monocytogenes* as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups). ICMSF describes 15 different cases of sampling plans, with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11 and 12 would apply to the serious category, and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g., hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible; thus, increasing the stringency of the sampling plans is appropriate. Cases 10, 11 and 12

apply to foods for the general population, where the proportion of susceptible individuals is much lower; thus, the overall risk of illness is reduced. Recent risk assessments have demonstrated that low levels of *L. monocytogenes* in food pose little risk, even for the highly susceptible population.

For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of *L. monocytogenes* will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., the organism cannot grow), and for cases 12 and 15, conditions may increase the risk (e.g., foods in which *L. monocytogenes* can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in the table below, where n is the number of samples and c=0 means that none of the “n” 25-g samples can be positive for *L. monocytogenes*. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that *L. monocytogenes* is present at <1 in 25 g. **It is recommended that the 25 g. sample be analyzed separately and not composited. However, if compositing is to be done, composites of 25-g portions should not exceed a total of 125 g. in order to maintain the sensitivity of the method of analysis.**

Conditions reduce concern	Conditions cause no change in concern	Conditions increase concern
Case 10 n=5, c=0 Mean Concentration 1 cfu/32g	Case 11 n=10, c=0 Mean Concentration 1 cfu/83g	Case 12 n=20, c=0 Mean Concentration 1 cfu/185g
Case 13 n=15, c=0 Mean Concentration 1 cfu/135g	Case 14 n=30, c=0 Mean Concentration 1 cfu/278g	Case 15 n=60, c=0 Mean Concentration 1 cfu/526g

Where RTE products must be sampled (hold and test) under the rule, the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers. Since deli and hotdog products are ranked as the top causes of foodborne illness, the establishment producing these products should select these products to be sampled first. Sampling starts after the establishment has conducted corrective actions that are specifically designed to find the most likely cause of the contamination and controls are put in place to prevent recurrence.

Case 10 n=5, c=0	Case 11 n=10, c=0	Case 12 n=20, c=0
Products with continued decline in population due to antimicrobial or other formulation considerations such as pH, a_w , etc. Products in Alternative 1	Products that limit growth (< 1 log) due to antimicrobial or other formulation considerations such as pH, a_w , etc. Products in Alternative 2	Products that support growth and that will be stored refrigerated for an extended period of time. Products in Alternative 3
Case 13 n=15, c=0	Case 14 n=30, c=0	Case 15 n=60, c=0
As for case 10, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 1 intended for a hospital, nursing home or other higher risk population	As for case 11, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 2 intended for a hospital, nursing home or other higher risk population	As for case 12, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 3 intended for a hospital, nursing home or other higher risk population.

The number of samples recommended will be collected in 1 day and all affected products will be held during the testing period. Testing can be for *Listeria* spp. or *L. monocytogenes*. Any positive results from this follow-up testing (using the ICMSF approach) should lead to more significant investigations of the cause and of prevention before intensified follow-up testing. If samples tested positive for *Listeria* spp., the establishment should confirm for *L. monocytogenes* and if positive for *L. monocytogenes*, the product is considered adulterated. The establishment must conduct rigorous corrective actions, and other sanitation and HACCP type activities.

Establishments may send a letter or certification when they ship tested products to nursing homes, hospitals and other institutions with susceptible populations. Such a letter would indicate that product has been sampled and tested according to ICMSF recommendations. Establishments supplying nursing homes, hospitals and other institutions with the susceptible populations are expected to implement whatever additional controls and verification procedures are necessary to ensure that product is not adulterated.

ATTACHMENT 6

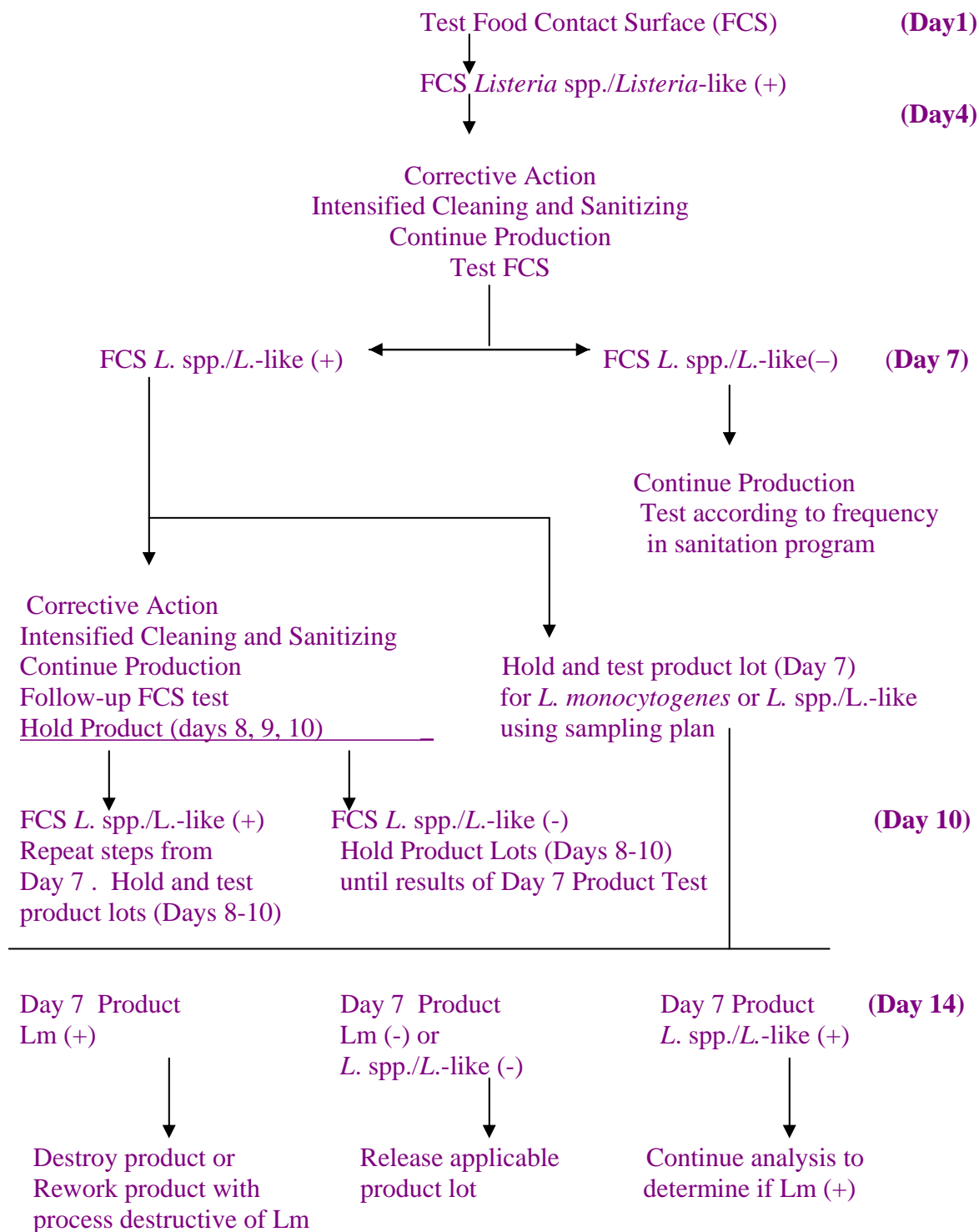
HOLD-AND-TEST SCENARIO FLOWCHART

The following flow chart is a most likely scenario for a hold and test situation. The flowchart illustrates what an establishment could do in case of a positive food contact surface (FCS) test, and when a follow-up FCS test is positive. Establishments can design their own procedures or flowchart for their hold and test program. Repeated positive FCS test would imply an inadequate sanitation system or harborage of the pathogen and establishments should investigate and reassess their sanitation program, their equipment layout and design product flow to determine the cause of the contamination.

This chart only addresses FCS testing with *Listeria* spp or *Listeria*-like organisms. If the establishment tests FCS for *L. monocytogenes* and result is positive, product in the sampled lot is considered adulterated. The establishment can destroy the product, rework the product with a process that is destructive of *L. monocytogenes*, or test product for *L. monocytogenes* and dispose of the product based on a sampling plan. In addition, the establishment must conduct follow-up testing starting from day 7 in the following chart.

ATTACHMENT 6

HOLD-AND-TEST SCENARIO FLOWCHART



FCS: food contact surface

L spp. or *L*.-like: *Listeria* spp. or *Listeria*-like organisms (test results available after 2 or 3 days)

Lm: *Listeria monocytogenes* (test results available after 6 or 7 days)

Enforcement strategy

Under 9 CFR 430, an establishment with deli and hot dog products in Alternative 3 must provide for testing of food contact surface (FCS). If the FCS tests positive for *L. monocytogenes* or *Listeria* Spp. or *Listeria*-like organisms, the establishment must conduct follow-up testing to verify its corrective actions. If during the follow-up testing another positive FCS occurs, the establishment must hold the applicable product lot if positive for *L. spp.* or *L*.-like, or destroy or rework with a process destructive of *L. monocytogenes* if positive for *L. monocytogenes*, and test the FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for *Listeria monocytogenes* using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a test and hold scenario which an establishment in this type of situation can use. The following section describes the likely action and reaction of inspection personnel during a hold and test situation.

Day 1, 4

The testing program and the test results for food contact and non-food contact surfaces should be available to inspection program personnel. In case of a FCS testing positive for *L* spp. or *Listeria*-like organism, inspection program personnel will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hot dog products in Alternative 3, inspection personnel will verify that the establishment is conducting follow-up testing for FCS to determine the effectiveness of the corrective actions, targeting most likely source of contamination and additional tests in surrounding FCS area, and recording all these.

Day 7

Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and sanitation program procedures. If the follow-up FCS tests are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms, inspection program personnel will verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel will verify whether the establishment is holding the product produced that day and testing the product lot for *L. spp.* or *L. monocytogenes*, and whether the establishment is conducting follow-up testing of FCS during each production, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9 and 10 are held until the follow-up FCS test available after about 3 days is found negative. The interim rule states that products must be held until the problem is corrected as indicated by testing. For establishments in Alternative 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed.

Days 8, 9, and 10

The presence of *Listeria* spp. or *Listeria*-like organisms on a food contact surface or on ready-to-eat (RTE) product is associated with the potential for an insanitary condition to exist. FSIS expects an establishment to develop a compelling justification for concluding that product produced on days in which insanitary conditions may have existed is not adulterated. Thus, FSIS would further expect that the establishment, on days 8-10 would conduct verification testing on the food contact surfaces to demonstrate that the potential insanitary condition was adequately redressed via the corrective and preventative actions. In addition, to further develop a compelling justification to support the establishment's decision, FSIS would expect a prudent establishment to also compile data on product testing to confirm and verify that the corrective and preventative actions were effective in preventing product from becoming adulterated.

Day 10If Day 7 FCS Test is Positive

Inspection program personnel will verify that if the follow-up FCS test taken on Day 7 is positive, then the day's production lots of deli and hotdog products in Alternative 3 are held and tested for *Listeria* spp./*Listeria*-like or *L. monocytogenes* and the same procedures are followed as in the second FCS (+) test as in Day 7.

If FCS samples taken on day 7 are found positive for *L. spp./L.*-like on day 10, the establishment should hold and test product produced on days 8, 9 and 10 unless the establishment has supporting documentation to justify that product produced on days 8, 9 and 10 would not be contaminated with *L. monocytogenes*. The sampling plan must provide a level of confidence that each product is not contaminated with *L. monocytogenes*. Because of 3 consecutive positive FCS, the establishment should conduct intensive cleaning and sanitizing and reevaluate its sanitation program.

If FCS is positive for *L. monocytogenes*, affected product lots are considered adulterated. The establishment should also hold and test products produced on days 8, 9 and 10 because a FCS positive for *L. monocytogenes* shows that the corrective action may not have been effective in removing the contamination and products produced on succeeding days may also be contaminated.

If Day 7 FCS Test is Negative

If FCS samples taken on day 7 are found negative for *Listeria* spp./*Listeria*-like on day 10, the establishment should wait for the results of the FCS tests conducted on days 8, 9, and 10 as detailed above, and results of the Day 7 product test before releasing these products. Products produced on days 8 and 9 may be released without waiting for product testing results if the establishment has a compelling justification for concluding that products produced on those days are not adulterated.

Day 14

If day 7 product was found positive for *L. monocytogenes* on day 14, affected product lots produced on day 7 are considered adulterated. The establishment must destroy the product lots or rework them with a process destructive of *L. monocytogenes*. The establishment should continue holding product lots produced on days 8, 9, and 10 until results of products tests are available, unless the establishment has supporting documentation for why product produced on days 8, 9 and 10 would not be contaminated with *L. monocytogenes*. Establishment should also test and hold product produced before day 7 and recall them if already in commerce or provide compelling evidence that product produced before day 7 was not adulterated.

For a product sample that tests positive for *L. monocytogenes*, inspection personnel will verify that the product lots affected are disposed properly, i.e., destroyed, or reworked with a process destructive to *L. monocytogenes*. Establishments should have supporting documentation that products lots produced before Day 7 are not contaminated with *L. monocytogenes*, so that these will not be included as adulterated.

A product that is positive for *Listeria* spp. or *Listeria*-like is not summarily determined to be adulterated, although it can lead to a determination that an insanitary condition exists and without compelling documentation, the establishment may not be able to conclude that the product is not adulterated. This also indicates that corrective and preventative actions taken may not have been effective, or that the sanitation program is inadequate and ineffective and therefore, the establishment needs to take actions to prove otherwise. The establishment needs to have compelling documentation that the product is not adulterated and needs to determine that its sampling plan provides a level of confidence that each product is not contaminated with *L. monocytogenes*.

If the establishment is using a post-lethality treatment or antimicrobial agent and the product tests positive for *Listeria* spp., *Listeria*-like organisms, or *L. monocytogenes*, according to 417.6(e), the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involved, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3.

The Agency will expect the same rigor for testing and sanitation at the point that product testing is reached for products in Alternative 3 and in Alternative 2, using an antimicrobial agent or process. For products in Alternative 1, and in Alternative 2 using post-lethality treatment, if FCS is positive for *Listeria* spp. or *Listeria*-like organisms product holding and testing may not be necessary as long as the post-lethality treatment is validated to reduce *L. monocytogenes* by at least 1 log, and the establishment verifies the effectiveness of the post-lethality treatment.